# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2010

# HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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## PART 7

## MEMBER BRIEFING—2009 H1N1 INFLUENZA PREPAREDNESS AND RESPONSE

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# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2010

WEDNESDAY, NOVEMBER 4, 2009.

## MEMBER BRIEFING—2009 H1N1 INFLUENZA PREPAREDNESS AND RESPONSE

### WITNESSES

**THOMAS R. FRIEDEN, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION**

**NICOLE LURIE, M.D., MSPH, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE**

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**ROB FULTON, DIRECTOR OF PUBLIC HEALTH, SAINT PAUL—RAMSEY COUNTY DEPARTMENT OF PUBLIC HEALTH, SAINT PAUL, MINNESOTA**

Mr. OBEY. Good morning, everybody. I wish we were not here today under these circumstances, but we have a problem that has, frankly, frustrated me, and I am sure a lot of other people, for at least the last 5 years.

Let me welcome subcommittee members and our panelists to this briefing on the H1N1 pandemic. Frankly, this committee, in my view, has had both a positive and negative effect on the issue of preparing the Nation against the threat of a pandemic.

Early on in 2005, President Bush requested $7.1 billion to boost vaccine production capacity, to stockpile antivirals, and boost State and local emergency preparedness. Congress responded by appropriating $1.1 billion less than the President requested.

Since 2007, it has been the flip side of that. This committee has been consistently pushing to do more than both the executive branch and the Senate appear to be comfortable doing.

In April of 2007, the committee proposed nearly $1 billion in supplemental funding for pandemic activities, but that investment never saw the light of day because that bill was vetoed.

In November of 2007, the committee tried again with $953 million in the regular fiscal year 2008 Labor-HHS bill, but that bill was also vetoed, and the end result of all of the yinging and yanging was a 70 percent cut in the amount that the committee tried to provide.

The committee tried again in January of 2009 with $420 million in the House version of the Recovery Act for pandemic preparedness, but even those limited resources met with resistance from the Senate. That provision was ultimately stripped from the final bill at the insistence of a number of Senators who asserted that pandemic funding had nothing to do with the economy and should not be in the final Recovery package.

Since the unexpected emergence of the novel H1N1 virus in April of 2009, we have been racing against the clock to get ahead of the virus. In the spring of 2009, the Obama administration requested $3.5 billion in emergency supplemental funding and requested some flexible authorities. In response the committee in June of 2009 provided an additional $7.7 billion to address this extraordinary challenge. The committee pushed hard for those investments because we wanted the country to be ready when the second wave of the pandemic hit.

The Nation has made significant strides since the initial outbreak of H1N1 flu, in no small measure due to the very people sitting before us here today, who have been working around the clock since April. Yet, despite some successes, so far the virus seems to be winning. According to CDC, some 48 States report widespread influenza activity. Nearly 6 million people have been affected, more than 21,000 people have been hospitalized, and more than 800 people have died, including at least 114 children.

In 2004, this committee on both sides of the aisle began asking questions about the insufficient supplies of vaccines and fluctuating demand for seasonal flu virus and the steps that the government could take to boost production levels, including guaranteeing some government purchases so that manufacturers could boost production levels and have an incentive to invest in new technologies.

I would urge members of the subcommittee to go back and take a look at our April 2004 subcommittee hearing and October 2004 subcommittee hearing on this issue, and I think you will have a clearer picture of why it is so frustrating to see how little progress we have made over that time in dealing with this production issue.

Five years later, it is clear that we are still using 1950s-era technologies and we are years away from state-of-the-art technologies that have been in use in other countries for at least a decade.

U.S. vaccine production capacity is still completely inadequate. H1N1 vaccine supplies are lagging far behind the need. By the end of the year, we still may not have enough vaccine to expand beyond covering high-risk groups to the general population.

Moreover, the country faces other public health challenges. For example, the distribution pipeline to States, local communities, and private providers for seasonal and H1N1 vaccines, antivirals and N95 respirators is plagued with rusty plumbing. Many providers have no idea how many of those critical supplies they will receive and when they will receive them. State and local health departments are further hampered in confronting this public health problem by steep budget shortfalls that have resulted in the loss of approximately 15,000 public health jobs since 2008. I find that number both disturbing and astounding.

With this briefing we hope that we can have a substantive and somewhat informal conversation with HHS State and local public

health officials so that we can ascertain exactly what the facts are regarding our current level of emergency preparedness at the Federal, State, and local levels so that we can understand how quickly response efforts can get ahead of the spreading virus instead of being behind the curve and identify the lessons learned to date so that we can be better prepared in the future.

When I was initially talking about this problem, I had intended to simply have a briefing for me, as chairman of the committee, to try to figure out what our problems were. But the more I thought about it, the more I thought we ought to simply have a briefing for the entire subcommittee.

Given the fact that there is so much public concern, so much public confusion about what the facts are, we thought that it would also be useful to invite—or at least provide access to whatever members of the press who wanted to participate, in the hopes that they perhaps could do a better job of conveying information to people than we have been able to do so far.

To keep this issue focused on substance and to try to keep it somewhat more organized than would usually be the case in a hearing setting, I have asked the staff to be prepared after our guests after they have made their comments, I am going to ask the staff to proceed to ask what they consider to be the most pertinent questions that need to be gotten out of the way. After that, we will turn to any member who wants to ask questions for five minutes until we are interrupted by so many roll calls that we wind up leaving in chaos, as is often the case when we are trying to get something done in competition with what is happening on the floor.

So let me simply ask Mr. Tiahrt if he has any comments he would like to make before we turn to our friends on the other side of the table.

Mr. TIAHRT. Thank you, Mr. Chairman. I think that we are where we are today. I think there is a tendency in Washington, D.C. to try to assess some sort of blame on why we are where we are today. But each administration gets about 4,000 people that they get to appoint and about 3½ million people work for the Federal Government. So the reason we are where we are, we can point a lot of fingers in a lot of directions.

Since we are moving into sort of a briefing format rather than a hearing, I just wanted to say that there are problems with the number of manufacturers we have in America. We have fewer now than we did a decade ago. I think some of that is based on what barriers the Federal Government has placed in front of creating businesses and keeping jobs here in America, excessive regulation, a tax structure that punishes success, it is the litigation system, and it is our failure to be energy independent.

When you add all these things together, it becomes less expensive to manufacture products that are necessary for the health and well-being of this country overseas. When we get overseas, for example, the New York Times has reported that the manufacturing of liquid flu antivirals similar to Tamiflu can be made, but we have not gotten approval from the FDA. So when we move jobs offshore and capacity offshore for building very important products like Tamiflu because of our own barriers created by this Federal Gov-

ernment and its elected officials, then we wonder how we get in these kind of situations.

I think what we ought to do now rather than try to assess blame is to move forward to find the best solutions to provide necessary things. We have some capacity. We have enough capacity to get the vaccine to our detainees in Guantanamo Bay, and yet we don't have you have enough for our seniors here in America. So I think we ought to move forward to figure out how we are going to recover from that because we do have millions of doses less than we thought we have.

I have other questions, but I am ready to move forward, Mr. Chairman.

Mr. OBEY. Mr. Lewis.

Mr. LEWIS. Thank you, Mr. Chairman, just for recognizing me.

The last time we were in session like this I had my first introduction to Doctor Gerberding. I must say we said many of the same things you raised. There is little doubt this is a big, big challenge, and I would hope we can proceed with this briefing with as little partisan politics as possible.

Mr. OBEY. Let me simply say that this briefing is not about blame. We are all on the same side. And I know everybody is doing their best and we are all a whole lot better at predicting the past than we are the future. We are simply interested in what is happening. We would like to take a hard, frank look at any things that need to change in the future in order to strengthen our capacity to deal with this in the future.

With that, let me simply ask each of you to take roughly five minutes and simply give us whatever comments you would like to give us before we move to staff questioning and then member questioning.

Let me simply run through the list of persons who will be giving us information. First, we will have Dr. Tom Frieden, who was named Director for the Centers for Disease Control and Prevention in June 2009, and is leading the work on the H1N1 virus. Second, Dr. Nicole Lurie, who was named the Assistant Secretary for Preparedness and Response in July 2009, and has the responsibility for coordinating all emergency preparedness and response activities at HHS.

Then, Dr. Tony Fauci, who is well known as the Director of the National Institute of Allergy and Infectious Diseases. Dr. Fauci, together with Dr. Lurie, is leading HHS efforts on vaccine development and safety.

Fourth, Dr. Donald Williamson is the State Health Officer in Alabama, the Alabama Department of Public Health. He will be introduced by Congressman Bonner.

Finally, Mr. Rob Fulton, Director of St. Paul—Ramsey County, Minnesota Department of Public Health, who will be introduced by Congresswoman McCollum.

In addition, we have in the audience Dr. Karen Midthun in case there are any questions pertaining to the FDA.

Why don't we begin with Dr. Frieden.

OPENING STATEMENT

Dr. FRIEDEN. Thank you very much, Mr. Chairman, Ranking Member Tiahrt, and members of the committee. The influenza virus is the enemy, and it is a difficult one to deal with. It is difficult to predict, it changes rapidly, and has the potential to cause enormous illness and death. Our way to address this issue is, as you said, Mr. Chairman, dated and requires updating.

I am pleased to have been asked to work under the leadership of Secretary Sebelius to ensure that the administration implements a comprehensive plan to address H1N1 throughout this season.

I bring to this the experience of having been Health Commissioner in New York City during the spring and having experienced firsthand the enormous challenge in terms of the number of cases, the challenges to the health care systems and hospitals, and the illness and death H1N1 can cause.

First, to briefly update you on where we stand with the situation. As you mentioned, Mr. Chairman, the virus continues to spread widely. It is now widespread in 48 States. There have been as of now many, many millions of cases of H1N1 influenza in this country. We have had well over 20,000 hospitalizations and more than a thousand deaths, including, as you mentioned, 114 at least among children. Those deaths, in terms of the pediatric deaths, adult deaths, and hospitalizations, are based on estimates. A little counterintuitively, sometimes the most accurate information is actually from estimations, particularly for hospitalizations.

H1N1 PATTERN OF ILLNESS

So far, there has been no change in the pattern of illness. H1N1 is not more severe than seasonal flu. Ninety percent of deaths from seasonal flu are among the people over age 65. Ninety percent of the deaths in H1N1 are people under the age of 65. This is a younger people's disease. In addition, it disproportionately affects people who have underlying conditions. More than two-thirds have had more than one or more underlying conditions, whether it is asthma, diabetes, lung disease, or heart disease.

I would comment that the increase in obesity and diabetes is not helping us here, and our need to address that more effectively is very important.

As there has been no change in the pattern of illness, there has been no change in the genetic pattern of H1N1. At CDC, we collect from around the country and around the world samples which undergo rigorous genetic testing, so we actually sequence to see if there are changes and monitor for the speed with which the virus has changed, because we know it will change. All influenza viruses evolve and mutate.

H1N1 FLU COMMUNICATION

We have at this point not seen significant changes. And that is important because it means that the vaccine which is being produced is an excellent match for this virus and that the level of virulence or how deadly this strain is has not increased. It is not becoming more deadly.

Only time will tell what the future holds—how long the current wave will continue, how many months, how many places, how high it will go, and whether, when it recedes, we will have another wave or another strain of H1N1 this flu season.

Flu season lasts until May. CDC's role, much of which has been made possible with the additional support from Congress over the past several years, has been to identify and characterize the virus, to develop a vaccine strain, to rigorously monitor the spread of the disease in the U.S. and globally, and then to coordinate response through communication—simple things: Staying home, covering cough, washing hands—and detailed guidelines for key sectors—businesses, health care settings, schools—trying to ensure that, to the greatest extent possible, while protecting the public health, we support people continuing to go about their business and help kids continue learning, people continuing working, and ensure that workplaces are as safe as possible.

H1N1 FLU VACCINATION CAMPAIGN

With treatment—we have to emphasize that there is effective treatment. Unfortunately, many people who should be getting treated aren't. Only half of people with diabetes or asthma who had influenza-like symptoms went to a provider at all. So we need to continue to get the message out that if you are severely ill or if you have an underlying condition, such as asthma or diabetes, it is important that if you have the flu, you see your provider promptly.

Not everyone who has the routine flu needs to be tested, but for those who have an underlying condition or are severely ill, it is important.

Here, also I think we have challenges in our health care system in terms of its coordination, its information systems, and its focus on prevention.

The vaccination campaign is an unprecedented effort. We have substantial amounts becoming available, but not nearly as much as we thought would be available or hoped would be available. With 20–20 hindsight it is clear we should have been more skeptical about the projections that were being made by vaccine manufacturers and we anticipated that having five different manufacturers would have provided more insurance than it has. It is important to ensure that the vaccine that we do have gets to people who need it as rapidly as possible.

RESPONDING EFFECTIVELY TO H1N1 FLU

We have taken no shortcuts in terms of safety and we are rigorously monitoring for any potential problems with the vaccine. We said in September that there would be bumps in undertaking this effort, and indeed that is the case. But we are working very hard with our partners throughout the U.S. Government and, most importantly, relying on State, local, and tribal health departments, health care institutions, and the public to address this as a shared responsibility that everyone can do something to address.

We are faced with the challenges that you mentioned with State and local infrastructure, which have significant problems with laboratory capacity, workforce challenges, and resources available. We are committed to doing everything we can to respond as effectively

as we can and also communicating rapidly and openly with the Congress and the public.

Thank you.

[The statement of Dr. Frieden follows:]

**Statement before the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies**
**United States House of Representatives**

# 2009 H1N1 Influenza Preparedness and Response

*Thomas R. Frieden, M.D., M.P.H.*
*Director,*
*Centers for Disease Control and Prevention*
*U.S. Department of Health and Human Services*

**For Release upon Delivery**
**Expected at 10:00 a.m.**
**November 4, 2009**

Chairman Obey, Ranking Member Tiahrt, members of the Committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza. CDC and our colleagues throughout the Department of Health and Human Services (HHS) are working in close partnership with many parts of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned this previous spring, as well as on preparedness training CDC has developed for pandemic influenza over the past several years. Working together with governors, mayors, tribal leaders, state and local health departments, the medical community and our private sector partners, we have been monitoring the spread of H1N1 and facilitating prevention and treatment, and have now begun a vaccination program.

Influenza is probably the least predictable of all infectious diseases and the 2009 H1N1 pandemic has presented considerable challenges—in particular the delay in production of a vaccine. Today I will update you on the overall situation, provide an update on vaccination status, and discuss other steps we are taking to address these challenges.

**Tracking and Monitoring Influenza Activity**

Since the initial spring emergence of 2009 H1N1 influenza, the virus has spread throughout the world. H1N1 was the dominant strain of influenza in the southern hemisphere during its winter flu season. Data about the virus from around the world—much of it collected with CDC assistance—have shown that the circulating pandemic H1N1 virus has not mutated significantly since the spring and the virus remains very closely matched to the 2009 H1N1 vaccine. This virus remains susceptible to antiviral drugs with very rare exception.

Unlike in a usual influenza season, flu activity in the United States continued throughout the summer, at summer camps and elsewhere. More recently, we have seen widespread influenza activity in 48 states; any reports of widespread influenza this early in the season are very unusual. Visits to doctors for influenza-like illness as well as flu-related hospitalizations and deaths among children and young adults also are higher than expected for this time of year. We are also already observing that more communities are affected than those that experienced H1N1 outbreaks this past spring and summer. Almost all of the influenza viruses identified so far this season have been 2009 H1N1 influenza A viruses. However, seasonal influenza viruses also may cause illness in the upcoming months—getting one type of influenza does not prevent you from getting another type later in the season.

Because of the current H1N1 pandemic, several additional systems have been put in place and modified to more closely monitor aspects of 2009 H1N1 influenza. These include the following:

- *Enhancing Hospitalization Surveillance:* CDC has greatly increased the capacity to collect detailed information on patients hospitalized with influenza. Using the 198 hospitals in the Emerging Infections Program (EIP) network and 6 additional sites with 76 hospitals, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group to monitor the clinical course among persons with severe disease requiring hospitalization.
- *Expanding Testing Capability:* Within two-and-a-half weeks of first detecting the 2009 H1N1 virus, CDC had fully characterized the new virus, disseminated information to researchers and public health officials, and developed and begun shipping to states a new test to detect cases of 2009 H1N1 infection. CDC continues to support all states and

territories with test reagents, equipment, and funding to maintain laboratory staff and ship specimens for testing. In addition, CDC serves as the primary support for public health laboratories conducting H1N1 tests around the globe and has provided test reagents to 406 laboratories in 154 countries. It is vital that accurate testing continue in the United States and abroad to monitor any mutations in the virus that may indicate increases in infection severity, resistance to antiviral drugs, or a decrease in the match between the vaccine strain and the circulating strain.

- *Health Care System Readiness:* HHS is also using multiple systems to track the impact the 2009 H1N1 influenza outbreak has on our health care system. HHS and CDC are in constant communication with state health officials and hospital administrators to monitor stress on the health care system and to prepare for the possibility that federal medical assets will be necessary to supplement state and local surge capabilities. To date, state and local officials and health care facilities have been able to accommodate the increased patient loads due to 2009 H1N1, but HHS is monitoring this closely and is prepared to respond quickly if the situation warrants.

**Shared Responsibility and Science-Based Guidance**

Slowing the spread and reducing the impact of 2009 H1N1 and seasonal flu is a shared responsibility. We can all take action to reduce the impact flu will have on our communities, schools, businesses, and homes this fall and winter.

There are many ways to prevent respiratory infections; CDC provides specific recommendations for the general public, people with certain underlying health conditions, parents, pregnant women, caregivers, and seniors.

Some ways to combat the spread of respiratory infections include staying home when you are sick and keeping sick children at home. Covering your cough and sneeze and washing your hands frequently are also effective ways to reduce the spread of infection. Taking personal responsibility for your health will help reduce the spread of 2009 H1N1 influenza and other respiratory illnesses.

CDC has also issued 2009 H1N1 influenza guidance for schools, child care settings, colleges and universities, large and small businesses, and federal agencies. These comprehensive guidelines provide advice on how individuals and institutions can guard against the flu and mitigate its spread. Guidance has also been issued for healthcare providers about the (1) appropriate use of antiviral medications to treat patients who are at highest risk of complications from influenza and (2) infection control measures in health care settings.

Our recommendations and action plans are based on the best possible scientific information available. CDC is working to ensure that Americans are informed about this pandemic and consistently updated with information in clear language. The 2009 H1N1 pandemic is a dynamic situation, and it is essential that the American people are fully engaged and able to be part of the mitigation strategy and overall response. CDC will continue to conduct regular media briefings, available at flu.gov, to get critical information about influenza to the American people.

**Vaccination Campaign**

Vaccination is our most effective tool to reduce the impact of influenza. Despite rapid progress during the initial stages of the vaccine production process, the speed of manufacturing has not been as rapid as initially estimated.

CDC characterized the virus, identified a candidate vaccine strain, and our HHS partners expedited manufacturing, performed clinical trials, and licensed four 2009 H1N1 influenza vaccines all within five months. The speed of this vaccine development was possible due to the investments made by the Congress over the past four years as these contributions have helped CDC advance research and development, as well as providing the funding to ensure CDC has an adequate infrastructure to support these activities.

Pandemic planning had anticipated vaccine becoming available 6-9 months after emergence of a new influenza. 2009 H1N1 vaccination began in early October—5 months after the emergence of 2009 H1N1 influenza. Critical support from Congress resulted in $1.44 billion for states and hospitals to support planning, preparation, and implementation efforts. States and cities began placing orders for the 2009 H1N1 vaccine on September 30th. The first vaccination with 2009 H1N1 influenza vaccine outside of clinical trials was given October 5th. As of October 30th, there were a total of 26.7 million doses available for ordering. Although significant delays in vaccine production by manufacturers have complicated the early immunization efforts, vaccine will become increasingly available over the weeks ahead, and will become more visible through delivery in a variety of settings, such as vaccination clinics organized by local health departments, healthcare provider offices, schools, pharmacies, and workplaces. CDC continues

to offer technical assistance to states and other public health partners as we work together to ensure the H1N1 vaccination program is as effective as possible.

Since September 30th, although the number of H1N1 vaccine doses produced, distributed, and administered has grown less quickly than projected, states have begun executing their plans to provide vaccine to targeted priority populations. Although we had hoped to have more vaccine distributed by this point, we are working hard to get vaccine out to the public just as soon as we receive it.

H1N1 vaccines are manufactured by the same companies employing the same methods used for the yearly production of seasonal flu vaccines. H1N1 vaccine is distributed to providers and state health departments similarly to the way federally purchased vaccines are distributed in the Vaccines for Children program. Two types of vaccine are now available: injectable vaccine made from inactivated virus, and nasal vaccine made from live, attenuated (weakened) virus.

CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that 2009 H1N1 vaccines be directed to target populations at greatest risk of illness and severe disease caused by this virus. On July 29, 2009, ACIP recommended targeting the first available doses of H1N1 vaccine to five high-risk groups comprised of approximately 159 million people; CDC accepted these recommendations. These groups are: pregnant women; people who live with or care for children younger than 6 months of age; health care and emergency services personnel; persons between the ages of 6 months through 24 years of age; and people from ages 25 through 64 years who are at higher risk for severe disease because of chronic health disorders like

asthma, diabetes, or compromised immune systems. These recommendations provide a framework from which states can tailor vaccination to local needs.

Ensuring a vaccine that is safe as well as effective is a top priority. CDC expects that the 2009 H1N1 influenza vaccine will have a similar safety profile to seasonal influenza vaccine, which historically has an excellent safety track record. So far the reports of adverse events among H1N1 vaccination are similar to those we see with seasonal flu vaccine and not unexpected, but we will remain alert for the possibility of rare, severe adverse events that could be linked to vaccination. CDC and the Food and Drug Administration (FDA) have been working to enhance surveillance systems to rapidly detect any unexpected adverse events among vaccinated persons and to adjust the vaccination program to minimize these risks. Two primary systems used to monitor vaccine safety are the Vaccine Adverse Events Reporting System (VAERS), jointly operated between CDC and FDA, and the Vaccine Safety Datalink (VSD) Project, a collaborative project with eight managed care organizations covering more than nine million members. These systems are designed to determine whether adverse events are occurring among vaccinated persons at a greater rate than among unvaccinated persons. CDC has worked with partners to strengthen these vaccine safety tracking systems and we continue to develop new ways to monitor vaccine safety.

While the 2009 H1N1 influenza virus has been the focus of attention since the spring, it is important that we do not forget the risks posed by seasonal influenza viruses, which typically peak during the winter months. More than 36,000 people die each year from complications associated with seasonal flu. CDC continues to recommend vaccination against seasonal

influenza viruses, especially for all people 50 years of age and over and all adults with certain chronic medical conditions, as well as infants and children. As of the fourth week in October, 89 million doses of seasonal vaccine had been distributed. It appears that interest in seasonal flu vaccine has been unprecedented this year. Manufacturers estimate that a total of 114 million doses will be brought to the US market.

**Antiviral Distribution and Use**

In the spring, anticipating commercial market constraints, HHS deployed 11 million courses of antiviral drugs from the Strategic National Stockpile (SNS) to ensure the nation was positioned to quickly employ these drugs to combat 2009 H1N1 and its spread. In early October, HHS shipped an additional 300,000 regimens of the antiviral pediatric oral suspension to states in order to mitigate a predicted near-term national shortage indicated by commercial supply data. To address the shortages of pediatric antivirals, the Secretary authorized the release of the remaining 234,000 regimes of pediatric Tamiflu on October 29th. We will continue to conduct outreach to pharmacists and providers related to pediatric dosing and compounding practices to help assure supplies are able to meet pediatric demand for antiviral treatment.

Additionally, the FDA issued an emergency use authorization (EUA) on October 23rd, 2009 for the investigational antiviral drug peramivir intravenous (IV) to be used for certain hospitalized adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection.

**Closing Remarks**

CDC is working hard to limit the impact of this pandemic, and we are committed to keeping the public and the Congress fully informed about both the situation and our response. We are collaborating with our federal partners as well as with other organizations that have unique expertise to help CDC provide guidance to multiple sectors of our economy and society. There have been enormous efforts in the United States and abroad to prepare for this kind of challenge. Our nation's current preparedness is a direct result of the investments and support of Congress over recent years, effective planning and action by Federal agencies, and the hard work of state and local officials across the country.

We look forward to working closely with Congress as we address the situation as it continues to evolve in the weeks and months ahead. Again, Mr. Chairman, thank you for the opportunity to participate in this conversation with you and your colleagues. I look forward to answering your questions.

OPENING STATEMENT

Dr. LURIE. Good morning. Thank you, Chairman Obey, Ranking Member Tiahrt, and members of the subcommittee. I too am pleased to be able to talk to you today about our efforts to respond to H1N1 in the U.S., and I, too, would personally like to take the opportunity to thank the committee for its continued support through the investments you have outlined, and despite the frustrations, we began rebuilding the vaccine infrastructure in this country several years ago, and as a result, when we decided to pursue vaccine in the spring, we actually had preexisting contracts in place with manufacturers already licensed here, enabling us to get out of the box quickly with contracts to manufacture the vaccine.

My office, as you alluded to, has a four-fold role related to this pandemic. First is to coordinate the HHS response and to work with the interagency. Second is to stimulate the development of and contract for the vaccines and antivirals. Third is to ensure that we can information back out to States and communities as we get vaccine rolled out. Fourth, and importantly, to stay prepared for any other emergency.

The H1N1 effort has been a public-private partnership. In terms of vaccine, I think, as you heard, we have developed this new vaccine with really unprecedented speed, and this was made possible by a whole series of investments and I want to say, in basic and clinical science, in manufacturing capacity and in regulatory processes. And obviously vaccine would not have been possible without our important partnerships with industry.

But while modest amounts of vaccine came a little bit ahead of schedule, a combination of poor production yield, late completion of seasonal vaccine, some problems in new filling lines, decisions in manufacturing, all combined to cause delays in the availability of the vaccine, and I will point out not just for the United States, but for the world.

The number of doses that has been produced, distributed, and administered continues to grow steadily. As of today, States have available 32.3 million doses and more are expected by the end of the week. But we also have to remain vigilant to ensure the steady supply of vaccine. We talk with the manufacturers every week, if not every day. We conduct site visits to our manufacturing partners to see what is going on and talk about how we can work together, and we have just completed a round of visits this past week. And we monitor the progress at every single lot of vaccine produced.

Last week, Secretary Sebelius and I spoke directly with the CEOs of each of the manufacturing companies, seeking to identify opportunities to work together to speed the delivery of vaccine. And while these delays are frustrating to everyone, they reinforce, as I think you already pointed out, the need to address our country's domestic manufacturing capacity using newer, faster, and more dependable technologies. And we need to do this as soon as possible.

Antivirals have been another critical aspect of our response. Here, we have supported the development of new antivirals, issuing an emergency use authorization for the first ever intravenous antiviral medicine and we are procuring over 30,000 treatment courses of IV antivirals to treat critically ill patients.

We are also focused on ensuring that the health care system and communities throughout the country remain able to care for those who need it.

You know, the President's declaration under the National Emergencies Act was a proactive step, enabling CMS to issue 1135 waivers to hospitals and other facilities if they are getting overwhelmed. And we stand ready to deploy federal assets when necessary, including clinical staff, vaccination teams, laboratory support and temporary medical facilities.

We've partnered closely with the private sector and health care systems, including health insurers, pharmacists, big-box stores, the AMA, public health authorities, to find a way to pay for vaccine administration so cost is not a barrier.

Let me turn for a minute to some of the lessons learned. The support of Congress in the last few years has been critical, enabling us to respond to this pandemic. And yet it is clear that public investment in health, whether at the Federal, State or local level, has real-world consequences, and we can't afford to let this happen again.

While we have made vaccine in record time, as Dr. Frieden said, our original projections were based on seasonal flu and H5N1 vaccines, and we were optimistic in the face of what has proved to be a bigger challenge by Mother Nature.

However, we are also far from done with the science and advanced development related to vaccines and building robust manufacturing capacity in the U.S. In other words, underinvestment in advanced development and infrastructure is also critical. My fear is that when this is all over, some will decide we don't need to worry about a pandemic for the next 30 years. Nothing could be more dangerous.

So despite the challenges, I believe that much of what we've learned from this pandemic will serve us well in the future as well as strengthen day-to-day public health.

Thank you.

[The statement of Dr. Lurie follows:]

**Statement**
**Committee on Appropriations**
**Subcommittee on Labor, Health and Human Services, Education, and Related Agencies**
**United States House of Representatives**

# Safeguarding our Nation: HHS Response to the H1N1 Outbreak

*Statement of*
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***Assistant Secretary for Preparedness and Response***
***U.S. Department of Health and Human Services***

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Good morning Chairman Obey, Representative Tiahrt, and Members of the Subcommittee. I am Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). As Secretary Sebelius emphasized in her testimony before the Senate in October, slowing the spread and reducing the impact of 2009 H1N1 is a shared responsibility, and we all need to plan for what would need to be done as the flu impacts our communities, schools, businesses, and homes this fall. I appreciate the opportunity today to discuss our role as well as some of the challenges and successes we have encountered in responding to the 2009 H1N1 influenza outbreak.

Before I go further, let me take the opportunity to thank the Committee not only for the rapid appropriations to respond to this current influenza threat but also for the foresight in providing significant resources since FY 2006 to lay the foundation for our Nation's pandemic preparedness. As you have seen in the semiannual and monthly reports, these resources have demonstrated a strong return on investment and have dramatically improved our ability to respond. However, our work in this area is far from done. We look forward to working with you in the future to continue to build our response capabilities not only for an influenza virus but also the wide range of natural and manmade threats that we face.

**Overview of the Outbreak**

Since the initial spring outbreak of 2009 H1N1 influenza, this virus has triggered a worldwide pandemic, and was the dominant flu strain in the southern hemisphere during that hemisphere's winter flu season. Data about the virus from around the world have shown that the circulating pandemic H1N1 virus has not mutated significantly since the spring. The virus remains similar to the virus chosen for the 2009 H1N1 vaccine, and remains susceptible to the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza), with rare exception. As with seasonal influenza, persons with some chronic health disorders and pregnant women have a higher risk of severe disease. In contrast to seasonal influenza, elderly persons have proven less likely to contract the virus; nevertheless, many elderly persons who do contract the virus have had serious complications. Early treatment with antivirals is recommended for elderly persons as well as for pregnant women, others at high risk for complications, and for anyone who becomes seriously ill.

Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably among school-aged children and young adults. More recently, we have seen widespread influenza activity in almost all states. Visits to doctors for influenza-like illness are much higher than levels expected for this time of the year.

Over the next several months, seasonal influenza viruses may circulate along with the 2009 H1N1 influenza virus, and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal influenza, or other respiratory conditions based on symptoms alone. Because of this, close monitoring of viruses in the United States will be critical to ensure that the best guidance about treatment and prevention of influenza can be provided.

**Office of the Assistant Secretary for Preparedness and Response (ASPR)**

The Pandemic and All-Hazards Preparedness Act (the Act) designated the HHS Secretary as the lead Federal official for public health and medical response to public health emergencies and incidents covered by the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan, and created the Assistant Secretary for Preparedness and Response. Under the Act, ASPR plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our federal interagency partners.

*2009 H1N1 Task Force*

In July 2009, the White House National Security Staff (NSS) released the *National Framework for 2009 H1N1 Influenza Preparedness and Response (National Framework)* to ensure a coordinated and focused national strategy. In response, ASPR created the 2009 H1N1 Task Force to: coordinate and consolidate H1N1 strategic program activities; serve as the focal point for policy

coordination; and ensure that HHS's National Framework activities and accomplishments are reported to DHS according to NSS timelines.

The Task Force addresses the National Framework's four key capability "pillars:" surveillance, mitigation measures, vaccination, and communication and education. The Task Force meets regularly with me and the HHS Chief of Staff to review ongoing activities to ensure our successful execution of the National Framework strategy. The Task Force has closely collaborated with DHS to establish a Common Operating Picture (COP) for 2009 H1N1, a single display of relevant information to facilitate collaborative planning and to achieve situational awareness.

*ESF #8 Response Activities*

Under the National Response Framework, ASPR is responsible for coordinating the Emergency Support Function (ESF) #8 response – Public Health and Medical Services. ASPR provides the mechanism for coordinated federal assistance to supplement State, local, territorial and tribal resources in response to public health and medical care needs during an emergency.

Specifically with regard to the 2009 H1N1 influenza outbreak, ASPR coordinates the interagency public health and medical response activities through a series of twice-weekly ESF #8 calls. During these calls, HHS regional health administrators and regional emergency coordinators report updates on their

regions' pandemic influenza preparedness and response activities. Federal interagency partners also report their activities for group discussion and integration.

Other coordination activities include weekly calls between ASPR and the State health departments to discuss any challenges and issues that might necessitate federal assistance. ASPR has also conducted calls with intensive care physicians to better understand the clinical picture of patients requiring extensive care in hospitals and to share information and experience to help identify best practices to improve patient outcomes. One of our critical concerns is to prevent local healthcare system failures from becoming regional healthcare system failures. Proactive measures to support our local partners in preventing system failure include 1135 waivers to decompress overburdened hospitals and deploying federal assets (where necessary) including clinical staff, temporary medical facilities and the needed logistical support.

*Hospital Preparedness*

Since its inception in 2002, ASPR's Hospital Preparedness Program (HPP) has provided more than $3 billion to fund the development of medical surge capacity and capability at the State and local level. HPP funds are awarded to State and territory departments of public health, which in turn fund projects at hospitals and other healthcare entities. As a result, hospitals can now provide more beds; actually communicate with other responders through interoperable

communication systems; track bed and resource availability using electronic systems; protect their healthcare workers with proper equipment; train their healthcare workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises. Over the past three years, HPP awardees have been required to conduct at least one pandemic preparedness exercise each year.

As a result of Congress's investment in the Hospital Preparedness Program our hospitals are better prepared to respond to the current 2009 H1N1 outbreak. Since the inception of funding, pandemic influenza preparedness and development of alternative care sites have been two priorities of the HPP program. In 2007, $75 million was awarded to States and territories specifically for pandemic influenza planning, including pandemic exercises and purchases of equipment, such as ventilators, that would aid in their response to a pandemic. Of the grantees receiving these funds, 79% conducted pandemic influenza exercises to hone their preparedness capabilities. In 2009, $90 million was awarded from the Supplemental Appropriations Act, 2009 for purchase of personal protective equipment, such as N-95 respirators for healthcare workers, and to develop plans for alternative care sites. Each program recipient was also required to develop plans for alternate care sites. CDC has also been providing support to States for vaccine program implementation and to help State and local health departments.

HPP has required recipients to implement a system of bed counting, called the "Hospital Available Beds in Emergencies and Disasters" (HAvBED). This system requires reports of available beds, including a count of available adult and pediatric general beds and ICU beds, to State and HHS emergency operations centers within four hours of request. For the past six weeks, HAvBED has been operational and collecting information from States about hospital status and has enhanced our 2009 H1N1 medical surge response.

Furthermore, based on the lessons learned from the spring 2009 H1N1 response, HAvBED was modified to also collect information on emergency department stress and hospital stress. ASPR worked with the HPP grantees, the American Hospital Association and private vendors to develop a core set of measures (including daily census counts and equipment shortages) for the level of stress on the healthcare system. Within 48 hours of receiving information, we have senior ASPR experts discuss and analyze data to determine if any hospitals are showing signs of stress or if there are indicators of equipment shortages. On occasions where the data indicates stress, we engage our Regional Emergency Coordinators to work with State health departments in conducting an investigation. To date, state and local officials have been able to accommodate the increased patient loads, but this is something we monitor very closely, and are prepared to respond quickly if the situation warrants. In addition, the declaration by the President of H1N1 as a national emergency, coupled with the Secretary's Declaration of a Public Health Emergency, allows us to temporarily

waive legal provisions or modify certain Medicare, Medicaid, CHIP, and HIPAA requirements under the Secretary's waiver authority under Section 1135 of the Social Security Act. This authority can provide hospitals with additional flexibility in certain circumstances to deal more effectively with patient surge rather than restrictive paperwork. This move has been welcomed by local hospitals many of whom can now make requests of the Centers for Medicare and & Medicaid Services for 1135 waivers in anticipation of increased patient loads. These requests are being reviewed and can be granted retroactively to the beginning of the emergency period (that is, back to October 23, 2009) if needed.

*Other Activities*

ASPR is working with the Society for Critical Care Medicine and is conducting a ventilator survey that will enable HHS to understand how many ventilators are available and where any regional shortages might exist. We are also working with professional organizations to train physicians in taking care of patients on ventilators.

The National Disaster Medical System (NDMS) is training personnel to become vaccinators to assist State and local jurisdictions in that activity. Additionally, NDMS teams have received training on the 2009 H1N1 outbreak and are standing by, ready to assist States/locals in the delivery of care to pandemic influenza patients or to augment non-flu treatment needs so that hospitals can divert their internal resources to H1N1 if needed.

**Responding to H1N1**

Responding to 2009 H1N1 influenza has provided challenges and valuable lessons that will assist our response efforts going forward. As this emergency unfolded, it became clear that significant resources would be necessary to respond to the pandemic with potentially large impacts. Further, based on a number of factors such as state readiness and vaccine effectiveness, we would not be able to plan response requirements with certainty and thus, how resources would need to be allocated. As a result, we greatly appreciate the flexible funding that the Congress provided for these efforts.

As we learn from the experiences of 2009 H1N1, we look forward to working with you to improve strategies to ensure that our Nation has the right assets at the right time to minimize the health impacts of an influenza pandemic, hurricane or bioterrorism event. The timely access to a flexible response fund has provided us with a nimbleness to quickly augment capabilities – such as hiring personnel on the front line of public health – where the speed of our response translates to lives saved.

Now, I will briefly discuss both our response efforts and a few of the challenges we encountered in our vaccine research and development, antiviral stockpiling, situational awareness, private sector collaboration, and international assistance.

*Vaccine Research and Development*

ASPR's investment over the past six years in medical countermeasure advanced research and development enabled the Department to complete 2009 H1N1 vaccine development with unprecedented speed. ASPR's Biomedical Advanced Research and Development Authority (BARDA) has worked with industry to build and sustain a domestic manufacturing infrastructure. Under the *HHS Pandemic Influenza Plan* (November 2005), the Department's key goals for vaccine preparedness were:

- Stockpile enough pre-pandemic influenza vaccines to cover 20 million persons in the critical workforce;
- Develop sufficient domestic manufacturing capacity to produce pandemic vaccine for the entire U.S. population of 300 million persons within six months of pandemic onset.

To establish domestic pre-pandemic influenza vaccine stockpiles, BARDA supported the development and manufacture of vaccines against different H5N1 avian virus strains. Today, BARDA continues to support a secure supply of raw materials, including eggs for domestic manufacturing of seasonal and novel influenza vaccines and the development and manufacturing of novel influenza vaccine candidates for clinical evaluation. BARDA also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing vaccine manufacturing facilities and building new cell-based influenza vaccine manufacturing facilities. Additionally, FDA was fully engaged

with industry to substantially increase the number of US licensed seasonal influenza vaccine manufacturers and their overall production capacity, a necessary infrastructure for pandemic vaccine development and production. It was through the licensed seasonal influenza vaccine framework that we were able to license and rapidly make available H1N1 vaccine.

The rapid responses of HHS agencies, including CDC, the National Institutes of Health, and the Food and Drug Administration, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by preparedness efforts for influenza pandemics set in motion by the H5N1 outbreak in 2003. Stockpiling for pandemic preparedness began in 2004, with H5N1 vaccine (23 million doses). In 2005 and 2006, the first six contracts for cell-based vaccines were initiated with manufacturers at a cost of $1.3 billion. In 2007, two manufacturers were contracted for work on adjuvants, which are vaccine-boosting compounds ($137.5 million). Throughout, clinical studies have been supported by ASPR/BARDA and the National Institutes of Health/ National Institute on Allergy and Infectious Diseases (NIH/NIAID).

These initial activities to prepare for H5N1 provided valuable lessons that have informed our efforts to respond to the current 2009 H1N1 outbreak. For example, we learned that coordination between ASPR/BARDA and NIH/NIAID and FDA was necessary to learn about the immunogenic properties of the virus and to conduct clinical trials. Working with our industry partners, we learned that,

just as for seasonal influenza vaccines, one dose of the H1N1 vaccine induces a response that is likely to be protective in adults and older children. We also learned that vaccine distribution through Points of Distribution (POD) should not be the only option. Instead, we need to develop our planning and contractual relationships to allow for flexible distribution--in this case, through a third-party--to 150,000 State-specified locations.

Since September 30, when the 2009 H1N1 vaccine was first made available to states to distribute, the number of doses that has been produced, distributed, and administered has grown steadily, and states are executing their plans for providing vaccine to high-priority populations. Our goal is to ensure that everyone who wants to get vaccinated will ultimately be able to do so. While modest amounts of vaccine have been made available ahead of schedule, poor production yields with the initial vaccine strains; late completion of seasonal influenza vaccine manufacturing; equipment failures on new production lines have caused significant delays in the manufacturers' timelines; and international competition which has reduced the amount of H1N1 vaccine available when two countries where vaccine is manufactured claimed priority for their vaccine. These delays are affecting both the U.S. and global H1N1 vaccine supplies. Manufacturers assure us they are taking active steps to overcome the remaining challenges, and we are doing all in our power to help them.

Moreover, BARDA conducts regular site visits to the vaccine manufacturers – completing two last week – and constantly monitors the progress of every lot produced, working to make up ground wherever possible. Also, FDA visited a third manufacturer last week. Finally, on October 29, Secretary Sebelius personally spoke with the CEOs of each of the five manufacturers to emphasize the importance of accelerating production in the coming weeks.

Our experience with the ups and down of the vaccine manufacturing process has made clear the need to enhance our country's vaccine manufacturing capability. Going forward, HHS planning efforts will continue to support the advanced development of seasonal and pandemic influenza vaccines. In 2005 and 2006, the first six contracts for advanced development of cell-based influenza vaccines were initiated. Several of these contractors have made significant advances toward U.S. licensure of their cell-based influenza vaccines. In 2008 one of these contractors started to build a new state-of the-art cell-based influenza vaccine manufacturing facility with a surge production capacity of 150 million doses of pandemic vaccine in six months using HHS/ASPR support. Additionally, HHS is supporting the advanced development of a recombinant influenza vaccine, which promises to have a shorter timeframe for production of pandemic vaccines and expects to fund development of more recombinant vaccines soon. HHS also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing domestic

vaccine manufacturing facilities, securing year-round supply of eggs and other supplies for existing U.S.-based egg-based facilities, and supported the construction of new U.S.-based cell-based influenza vaccine manufacturing facilities. These investments will advance U.S. pandemic preparedness goals and decrease dependence on foreign manufacture of influenza vaccines.

*Antiviral Stockpiling*

Under the *HHS Pandemic Influenza Plan*, HHS was required to:

- Establish national influenza antiviral drug stockpiles to treat 25 percent of the U.S. population during a pandemic, plus an immediate readiness cache of 6 million treatment courses for containment at pandemic onset;
- Support the advanced development of new and promising influenza antiviral drugs toward U.S. approval; and
- Boost U.S.-based production of antiviral drugs.

To accomplish these mandates, ASPR awarded contracts in 2004-2007 totaling more than $924 million to establish and coordinate the federal and State pandemic stockpiles of antiviral drugs. We procured 50 million treatment courses for storage in the Strategic National Stockpile (SNS) by the end of 2007, completing the federal contribution to the antiviral goal. Additionally, using funding provided by Congress, ASPR subsidized States in their purchase of 25

million treatment courses of antivirals towards the 31 million treatment course goal for State stockpiles.

In the spring, anticipating commercial market constraints, HHS deployed 11 million courses of antiviral drugs from the Strategic National Stockpile (SNS) to ensure the nation was positioned to quickly employ these drugs to combat H1N1 and its spread. This action has been effective in allowing the nation to deal with spot shortages of antiviral drugs and limitations on supplies of products targeted for young children, including liquid preparations authorized for emergency use in infants less than 1 year of age. To replenish the SNS, HHS purchased 13 million treatment courses ($260 million) of Tamiflu® (10.4 million treatment courses) and Relenza® (2.6 million treatment courses). In October, HHS made available to states an additional 300,000 regimens of the antiviral pediatric oral suspension to mitigate a predicted near-term national shortage indicated by commercial supply data.

To support antiviral development and manufacturing ramp-up activities, BARDA awarded a contract in 2007 for $102.7 million for advanced development and domestic industrialization of a new influenza antiviral drug. Beginning in 2008, BARDA also solicited and awarded additional contracts for new and combination influenza antiviral drugs. These efforts directly benefited pediatric and critically ill populations.

We know that antiviral resistance is a threat. So our acquisition strategy for additional antivirals needed to be flexible. A lesson learned from the 2009 H1N1 outbreak is that rare cases of H1N1 have been Tamiflu resistant. As a result, ASPR has increased efforts to stockpile an alternative antiviral, Relenza. We also know from this outbreak that children are disproportionately affected by 2009 H1N1 influenza, leading us to procure more pediatric courses of antivirals.

Another challenge presented by 2009 H1N1 influenza is the treatment of critically ill individuals, who potentially may require an intravenous antiviral formulation. Currently there are no influenza antiviral drugs approved for parenteral use (such as I.V.), a serious gap in our ability to effectively treat critically ill influenza patients. Since January 2007, HHS has supported the advanced development of a new antiviral drug, Peramivir, which may be administered intravenously to hospitalized influenza patients. These drugs provide dependable dosing for these patients who can experience nausea/vomiting and/or other gastrointestinal conditions that limit drug absorption. On October 23, an Emergency Use Authorization was issued by the FDA for the utilization of peramivir to treat critically ill patients with H1N1 virus infections. In addition, the potential for emergency use of intravenous formulations of two other antiviral drugs, approved already for other indications, is under evaluation. ASPR anticipates the

procurement of intravenous (I.V.) influenza antiviral drugs for stockpiling to be used under Emergency Use Authorization.

*Situational Awareness*

Situational awareness is an essential component of any incident response. During the 2009 H1N1 influenza response, HHS worked very closely with the Department of Homeland Security (DHS) to develop a National Situation Report (SitRep) which is then inserted into the Homeland Security Information Network (HSIN). Working cooperatively, DHS and HHS have modified the SitRep to accurately reflect public health and medical issues. HHS has also been working with DHS to enable State and local public health officials to gain access to the HSIN so they can maintain their situational awareness.

*Private Sector Collaboration*

HHS has engaged many private sector partners in a series of problem-solving dialogues related to the vaccine dispensing program. The Association of State and Territorial Health Officials (ASTHO) worked with ASPR to convene a series of meetings with America's Health Insurance Plans (AHIP), individual insurers, American Pharmacists Association, retail pharmacy chains, American Medical Association (AMA), National Vaccine Safety Program, and other State and federal partners. The private sector demonstrated a firm commitment to working through complex issues of vaccine administration, billing processes, and other policy issues that would facilitate a successful vaccine campaign with the goal of

providing easy access to the 2009 H1N1 influenza vaccine for every person in the United States who wants it.

Many issues related to vaccine administration, including billing and payment issues, were raised. Partnerships with the HHS Centers for Medicare & Medicaid Services and the AMA yielded the development of specific vaccine codes, and unique vaccine administration codes for both Medicare recipients and the privately insured. In addition, the health insurers and pharmacies agreed upon a set of principles for billing practices and payment procedures and developed associated draft templates to support State vaccine program consistency.

*International Assistance*

There is broad international recognition that the 2009 H1N1 pandemic is a global health challenge. Millions of people around the world have been affected, thousands have died and the virus continues to spread across international borders. Recognizing that 2009 H1N1 infection, like most diseases, knows no borders and that the health of the American people is inseparable from the health of people around the world, President Obama committed to make 10 percent of the US 2009 H1N1 vaccine supply available to other countries through the World Health Organization (WHO). Vaccine will be donated on a rolling basis, as it becomes available, in order to assist countries that will not otherwise have direct access to the vaccine. We are taking this action in concert with international

partners: Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, Japan, Germany, and the United Kingdom.

On October 5, we met with the Governments of Mexico and Canada to review current 2009 H1N1 efforts and decided to re-institute the North American Plan for Avian and Pandemic Influenza Coordinating Body to ensure continued international coordination in the areas of human health, animal health, border issues and emergency management. On October 31, Secretary Sebelius discussed efforts to coordinate donor contributions, maximize the impact of our collective efforts, and mitigate the effects of this pandemic on the poorest regions of the world with the World Health Organization (WHO) Director General, United Nations System Influenza Coordinator (UNSIC), United Nations Secretary General, and United Nations Children's Fund (UNICEF) Executive Director.

**Conclusion**

I want to assure the Subcommittee that the Administration is taking the public health challenges of 2009 H1N1 seriously and is implementing a comprehensive strategy to monitor and address this influenza outbreak throughout the fall and winter. HHS continues to work in close partnership with virtually every part of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned from this spring.

Working together with governors, mayors, tribal leaders, state and local health departments, the medical community, and our private sector partners, the federal government has been actively implementing a vaccination program and continues to revise and refine our pandemic influenza plans and activities based on new data and information.

It is important to reiterate that our current level of preparedness and subsequent ability to respond is a direct result of the investments and support of Congress; the hard work of State, local, tribal, and territorial public health officials; and our partners in the private and not-for-profit sectors. Building strong systems to track and monitor seasonal influenza has allowed us to closely monitor the impact of this novel virus on our communities.

Our Nation's investment in public health infrastructure, particularly at the state and local levels, remains a critical challenge that has real life consequences in. Today, these consequences are impacting our communities, our schools, our workplaces and our homes.

Investments in science and the public health infrastructure will enable us to better prepare and respond to threats, such as 2009 H1N1, that arise in the future. For instance, the President's 2010 budget includes funding for advanced development of antiviral drugs and invests in new vaccine technology. This will advance our on-going commitments to developing new cell-based and

recombinant vaccine production methods and help complete a domestic cell-based production facility, currently under construction here in the U.S. In addition, our work on new antivirals and important medical devices, including rapid diagnostics, continues to yield exciting results. These investments hold the promise of more effective treatments that can be developed over shorter timeframes and made available more quickly to families and individuals. It is also critical to increase investments in our State and local health departments, which have been chronically underfunded. We have made great strides in leveraging information technology to enhance surveillance of diseases threats, but need to increase our support for building the workforce of epidemiologists and other public health specialties that are vital to preventing, identifying and containing outbreaks. We also must ensure that we have the ability on the ground to reach at-risk populations with core public health interventions, such as communication strategies designed to mitigate the spread of disease and clearly define the risks of an emerging threat. This will pay dividends with more resilient communities that are better prepared for a flu pandemic and can withstand, absorb, and adapt to other public health incidents before they become emergencies. Moreover, these investments require our continued attention and commitment over the long-term and should not depend solely on the occurrence of a public health emergency. Our experience with 2009 H1N1, and the lessons we have learned, demonstrate a need to examine new paradigms for leveraging the public health infrastructure and our healthcares systems to develop the needed capabilities to

ensure every community is prepared to respond to and recover from future disasters.

Thank you for your time and interest. I am happy to answer any questions.

Mr. OBEY. Dr. Fauci.

OPENING STATEMENT

Dr. FAUCI. Thank you, Mr. Chairman, Ranking Member Tiahrt, members of the committee and staff, for giving me the opportunity to discuss very briefly with you the role of the NIH basic and clinical research endeavor in the comprehensive approach mounted by the Department of Health and Human Services and other government agencies in addressing the very daunting problem of this extraordinary pandemic.

As I have testified before this committee so many times in the past, the mandate of the NIH is to do basic and clinical research in a variety of diseases. For the purposes of today's discussion, infectious diseases in general, and specifically influenza. As shown on this placard on the left hand side (on your right) we have done and continue to do fundamental basic research and clinical research to address countermeasures, both therapeutics, diagnostics, and vaccines.

Today, we will focus on vaccines. I hope during the questions period we can get into the considerable investment that was really made possible by the generosity of this committee in giving us funds to do fundamental research to bring the technology or, as we call it, the vaccine "platforms" into the 21st century to get beyond having to grow the virus, but to actually do it with 21st century technology.

But, having said that, let me just focus for the next couple of minutes on the problem at hand and the activities that have occurred.

The process of getting a vaccine for this H1N1 pandemic started, as you heard from Dr. Frieden and Dr. Lurie, in April. That is very interesting, because we usually start this process in January when we make a prediction what the flu would be for the next season and we begin with an educated guess that is almost always correct about matching the virus with the vaccine. In this case, it was April. But this was done relatively quickly, but without cutting corners.

The CDC isolated the virus in April. Within a period of a couple of weeks, we at the NIH had seed viruses that we gave to our grantees to start looking at various components of this virus vis-a-vis its virulence, its transmissibility, et cetera. But more importantly, we partnered with the pharmaceutical companies that we had prearrangements with to get pilot lots to be given to our clinical trial units to ask some fundamental questions that were important in informing us about how to use this vaccine.

As shown on this next placard, this is a map of the United States with the eight vaccine and treatment evaluation units that are time-honored for decades and which the NIH continually uses to test drugs as well as vaccines for infectious diseases that reemerge, and newly emerging ones. They are extensively experienced. And what they have done over the last several months, I think, has been very important to informing us about the policy about how to use this vaccine.

So certain fundamental questions arise. Let me put it into perspective for you. You all remember, because I testified before this

committee when the H5N1 bird flu was upon us and continues to smolder. We made a vaccine that was FDA-approved. That was the good news. The sobering news is that it required an outlandish dose of vaccine to induce an immune response that we predict would be protective in even 50 percent of the people. That was not good news.

So our concern right off was: Is this vaccine going to induce an immunogenic response that you would predict to be protective?

So we asked a number of questions. First, in healthy adults, elderly, and children, does a dose that is comparable to the dose of seasonal flu induce a robust immune response? Does it require twice the dose; does it require two doses? And we were very pleased to see that in fact a single dose of 15 micrograms of unadjuvanted vaccine, meaning it doesn't have a compound that is necessary to amplify the response, was sufficient. We were successful in showing that in a very high percentage of these healthy individuals, in fact a single dose was required.

VACCINE TRIALS

We also had to look at children. This is very important because, as you know, the standard seasonal flu generally requires a single dose for older children between 10 and 17 and two doses for children from 9 years down to 6 months.

I announced just a couple of days ago that our vaccine trials in children showed that what the FDA and the CDC and our advisory committees have been advising for years and years with seasonal flu holds true also for this vaccine. A single dose for the older children and two doses for the children who are younger.

Importantly, pregnant women, about whom who we heard from Dr. Frieden, are particularly vulnerable to not only infection but to the complications of the infections. Again, just two days ago I announced that in pregnant women a single dose of 15 micrograms induced a very robust response that you would predict would be protective in those individuals. This is very good news for the pregnant women who have already been vaccinated and good news and encouragement for the pregnant women that are trying to get vaccinated. In addition, we have ongoing trials in HIV infected women and children and asthmatics.

With regard to clinical trials, we now know, and as you have heard from both Drs. Lurie and Frieden, we are concerned and frustrated by the gap between the demand and supply. But as people get vaccine available to them, we know how to use it.

I want to close just with one statement about the question I get asked and we all get asked so many times: What is the risk benefit? We have a very interesting, almost paradoxical situation where a high percentage of people don't want to get the vaccine and another high percentage that do, and this gap between supply and demand. So when people say: Is this vaccine absolutely safe; there is nothing in the world that is a hundred percent safe. You open up your door to go to work and go out on the Beltway, that is not absolutely safe. So rather than saying something is absolutely safe, you say what is the risk-benefit. And when you talk about risk of the vaccine, we have decades of experience of making

vaccines very similar, same company, same materials, same process. Antiquated as it may be, it is time-honored but it is fragile.

The risk historically is very small. We are in the middle of a pandemic and we see although the risk of serious disease is low, when it happens particularly to young children, people with underlying conditions, and pregnant women, it could be catastrophic. If you just look at this, the risk of getting infected and getting seriously ill, particularly among certain populations, is far greater than the risk of the vaccine. And it is for that reason that although we can't say it is 100 percent safe, we recommend that those people get the vaccine when it becomes available.

Thank you.

[The statement of Dr. Fauci follows:]

**Statement**
**Committee on Appropriations**
**Subcommittee on Labor, Health and Human Services, Education, and Related Agencies**
**United States House of Representatives**

# The Role of NIH-Supported Research in the Response to 2009 H1N1 Influenza

*Statement of*
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Mr. Chairman and members of the Subcommittee, thank you for the opportunity to discuss the NIH research response to the pandemic caused by the novel 2009 H1N1 influenza A virus, which the President declared to be a National Emergency on October 24, 2009.

Over the past several years, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS), has conducted a major research effort that builds on long-standing programs related to seasonal influenza in order to improve our preparedness for pandemic influenza. Although in this decade we have focused a good deal of attention on H5N1 avian influenza, it always has been clear that the next pandemic threat could come from another influenza virus altogether.

The new pandemic influenza virus is now here and is widely spreading throughout the globe. In response, NIH has intensified the implementation of the research agenda that underpins the development of countermeasures for all influenza subtypes, and in particular, the 2009 H1N1 virus.

In my remarks today, I will discuss the research response being mounted by NIH that is complementary to—and synergistic with—the efforts of other components of HHS such as the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and

Response, and our sister agencies, the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), as well as other organizations throughout the world.

**Seasonal and Pandemic Influenza**

Influenza viruses affect many animal species, including birds, pigs, and humans. As influenza viruses circulate, the genes that determine the structure of their surface proteins undergo small changes called mutations. These genetic changes accumulate over time to cause a gradual "antigenic drift" that allows an influenza virus in a typical influenza season to largely evade the preexisting immunity that a significant proportion of the population may have developed from prior exposure to influenza viruses or from prior vaccinations. Antigenic drift in human influenza viruses is the basis for the predictable patterns of seasonal influenza seen in most years and is the reason that we annually reassess and frequently change the strains to be included in the seasonal influenza vaccine.

In humans, seasonal influenza epidemics in the Northern hemisphere usually occur in winter months. According to the CDC, these seasonal events cause symptomatic illness in 15 to 60 million people in the United States every year; they result in an average of approximately 200,000 hospitalizations and 36,000 deaths. Residual or background immunity from prior exposure to related influenza viruses or from prior immunizations tempers the number of illnesses, hospitalizations, and deaths we see each year. Most of the severe outcomes

from seasonal influenza occur among people aged 65 years and older, in very young children, and in those with chronic health conditions. Globally, seasonal influenza causes 3 million to 5 million cases of severe illness each year, and an estimated 250,000 to 500,000 influenza-related deaths, according to the World Health Organization.

Influenza viruses also can switch hosts, from an animal source to humans, which can pose a more serious threat to human health. One way this could occur is through the infection of humans by a novel influenza virus from a non-human source. For example, influenza viruses infecting birds can, on rare occasions, also infect humans. Although the result is usually a "dead-end" infection that does not spread further, the virus might undergo mutations that allow limited human-to-human transmission. Once transmission begins, further mutation can make human-to-human transmission more efficient and sustainable. Another way that a novel influenza virus can circulate in humans is "antigenic shift" that occur through a process called reassortment, in which two virus strains co-infect a host and exchange genes resulting in a hybrid virus. Whatever the mechanism, the result may be the evolution of a new virus to which the human population has little or no immunity. If this new virus is able to efficiently transmit from human to human, then an influenza pandemic may result. An influenza pandemic is an unpredictable and rare event that can occur at any time of year.

In the 20th century, influenza pandemics occurred three times—in 1918, 1957, and 1968. The pandemics of 1957 and 1968 were serious infectious disease events that killed approximately two million and 700,000 people worldwide, respectively. The 1918-1919 pandemic, however, was catastrophic: epidemiologists estimate that it killed more than 50 million people worldwide, including more than 500,000 people in the United States, and caused enormous social and economic disruption.

Given this history, we long have expected that a new influenza virus would emerge and another pandemic would occur. Since the initial spring outbreak of a novel influenza strain, the 2009 H1N1 influenza virus, this virus has triggered a worldwide pandemic and emerged as the dominant influenza strain in the Southern hemisphere during its winter influenza season. Here in the United States, we continued to see influenza activity over the summer, which is totally unlike the pattern with typical seasonal influenza. More recently, we have seen a marked increase in 2009 H1N1 influenza activity in most states associated with the return of students to school, a trend we expect will continue in the coming months.

The U.S. Government, and HHS in particular, has been preparing for an influenza pandemic for many years. These efforts were bolstered after H5N1 avian influenza reemerged in Southeast Asia in 2003. U.S. Government pandemic preparedness plans assign to the NIH the primary responsibility for

scientific research and clinical trials needed to develop and test pandemic influenza vaccines and therapies.

For decades, NIH has supported basic influenza research to understand better how influenza viruses replicate, interact with their hosts, stimulate and evade immune responses, and evolve into new strains. Results from these basic research studies lay the foundation for the design of new therapies, diagnostics, and vaccines, and are applicable to seasonal epidemic and pandemic strains alike. NIH has worked with FDA and our partners at academic medical centers and in the biotechnology and pharmaceutical industries to speed development of new influenza vaccines, diagnostic tools, and anti-influenza drugs. We also have built a substantial infrastructure of research centers, NIH intramural and NIH-supported extramural laboratories, highly trained personnel, and clinical research networks to rapidly conduct research should a virus with pandemic potential emerge.

NIH is presently engaged in an accelerated effort to fully understand the currently circulating 2009 H1N1 influenza virus and to rapidly develop effective countermeasures. Scientists already have learned a great deal about the biology of the 2009 H1N1 virus, and we are taking numerous steps to learn more. NIH also has been fulfilling its role in developing vaccines and testing therapeutics to counter this newly emerged virus.

**Basic Science**

When the emergence of 2009 H1N1 influenza was first reported, scientists at CDC, FDA, NIH, NIH-supported laboratories, and elsewhere around the world obtained samples of the 2009 H1N1 virus. NIH immediately began a thorough and rapid characterization of the virus in cell culture and laboratory animals, as well as genetic and structural studies of the virus. That effort involved intramural researchers on the NIH campus, researchers in preexisting NIH research networks such as the Centers of Excellence in Influenza Research and Surveillance (CEIRS) and Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), as well as industry partners and individual NIH grantees.

These efforts already are yielding important information about the virus. For example, NIH-supported CEIRS researchers have found that the novel 2009 H1N1 influenza virus may have a biological advantage over seasonal influenza viruses in animal models. Preliminary findings in ferrets suggest that the levels of 2009 H1N1 influenza virus rise more quickly than seasonal influenza virus strains and that the 2009 H1N1 virus causes more severe disease. We expect that NIH-supported research will continue to provide critical insights into the mechanisms by which the virus causes disease, its molecular signatures of virulence and enhanced transmission, and the major viral and host factors important in mounting an immune response to the virus. NIH-supported researchers also are implementing a number of clinical studies to provide crucial

information about how the virus behaves in humans, how the human immune system responds to it, and how much cross-protection, if any, is provided by antibodies to previously circulating human H1N1 viruses.

**Vaccines**

Working with its partners in industry and academia, HHS agencies such as NIH, CDC and FDA have completed key steps in the development of vaccines for the 2009 H1N1 influenza—we have characterized the virus, identified a candidate strain, expedited manufacturing, and conducted clinical trials. HHS has contracted to purchase vaccine from five vaccine manufacturers who are producing either inactivated or live, attenuated H1N1 influenza vaccines by the same methods that are used annually for the production of seasonal influenza vaccines. The 2009 H1N1 vaccines from four of these manufacturers were approved by the FDA on September 15, 2009, for use in the United States. Inactivated vaccines are based on chemically killed influenza viruses and are injected intramuscularly, whereas live, attenuated vaccines are based on a weakened influenza virus and are administered as a nasal spray. The first lots of the 2009 H1N1 influenza vaccines became available in early October.

NIH has used its longstanding vaccine clinical trials infrastructure—notably our network of Vaccine and Treatment Evaluation Units (VTEUs)—to conduct a series of clinical trials to quickly evaluate pilot lots of 2009 H1N1 inactivated vaccines to assess their safety and ability to induce immune responses that are

predictive of protection. Data from these trials have helped to inform the development of recommendations for immunization schedules, including the optimal dosage and number of doses for individuals in different age brackets and for specific groups such as pregnant women. Close collaboration among NIH, FDA, and BARDA was critical in launching these studies quickly while ensuring the usual high standards for the conduct of clinical trials.

Trials to evaluate the safety and immune response of two different dosages (15 micrograms versus 30 micrograms) and one versus two doses of vaccine in healthy adults and the elderly began in the first week of August. As NIH announced on September 11, preliminary data indicate that the vaccines are safe and that a single 15-microgram dose induces what is likely to be a protective immune response in healthy adults between the ages of 18 and 64 years. For adults aged 65 and over, preliminary data indicate that the immune response to the 2009 H1N1 influenza vaccine is somewhat less robust, as is the case with seasonal influenza vaccine. These data are consistent with early data from independent studies conducted by several of the vaccine manufacturers. Complete immune response data from the trials studying two doses in healthy adults are expected in mid- to late November.

NIH is conducting similar trials in populations who are at higher risk of influenza complications, including children, in whom a trial began in mid-August, and in pregnant women, in whom a trial began in September. Early data from the

pediatric trials suggest that one dose of vaccine in older children, aged 10 to 17 years, may be adequate to induce a robust immune response. While we continue to evaluate data from our studies and those of the manufacturers, younger children generally had a less robust early response to just one dose of the vaccine and at this point will require two doses similar to the dosage recommendation for seasonal influenza in this age group.

NIH is conducting additional studies of the vaccines in other populations, including HIV-positive individuals and people with asthma. Two clinical trials to evaluate the 2009 H1N1 influenza vaccine in HIV-infected pregnant women, children, and youth began in October, with preliminary results expected in early 2010. The first patients with asthma were enrolled in a 2009 H1N1 influenza vaccine clinical trial in mid-October. Preliminary results from this trial are expected at the beginning of 2010.

A concurrent set of trials now underway will determine whether the 2009 H1N1 influenza vaccine and seasonal influenza vaccine can be administered at the same time or sequentially and whether both vaccines will induce protective immune responses. These trials are being conducted in healthy adult, elderly, and pediatric volunteers. Early data suggest that these vaccines can be co-administered without negatively impacting the immune response to either vaccine.

Finally, NIH is supporting trials of 2009 H1N1 influenza vaccines that contain adjuvants. Adjuvants are additives that help create a more vigorous immune response to a vaccine, thereby reducing the amount of antigen required per vaccine dose. Currently, it is not expected that adjuvants will be used in a U.S. vaccination program against 2009 H1N1 influenza. However, clinical trials are being conducted with adjuvanted vaccines as a contingency plan; an adjuvanted product might be needed, for example, if the virus mutates to become different from the vaccine virus, if certain populations do not mount an adequate immune response to vaccination, or if we need a larger supply of vaccine. The first adjuvant trial began in late September, with the first preliminary immune response data expected in mid-November.

NIH and its industry partners have been developing several other kinds of influenza technologies and vaccines that are not yet licensed for use. These include recombinant DNA technologies that yield subunit vaccines, in which various influenza virus proteins are selectively produced in cultured cells and are then purified and used in a vaccine; DNA vaccines, in which influenza genetic sequences are injected directly into a person to stimulate an immune response against the proteins coded for by these genetic sequences; and approaches that insert the genes of influenza virus into a different virus (a "vector") that is used as a vaccine. For example, a study of a prototype 2009 H1N1 influenza vaccine that relies on one of these experimental strategies is underway; the NIAID Vaccine Research Center is enrolling healthy adults in a clinical study of its DNA-

based H1N1 influenza candidate vaccine. In addition, NIAID's effort to support development of a novel purified hemagglutinin vaccine has recently resulted in a BARDA contract to further develop this product. Because such "next-generation" vaccines will require additional safety and efficacy testing before they can be deployed, and because, even if safety and efficacy are proven, scaling up to commercial levels of manufacturing is complex, they will not reach the public during the upcoming influenza season.

**Antiviral Therapies and Diagnostics**

Antiviral medications are an important counterpart to vaccines as a means of controlling influenza, by treating infection after it occurs and, under certain circumstances, by preventing illness prior to or immediately after exposure. There are three antiviral drugs currently available for treatment of influenza during the H1N1 pandemic. The 2009 H1N1 influenza virus is sensitive to oseltamivir (Tamiflu®) and zanamivir (Relenza®). In addition, an intravenous formulation of peramivir for treatment of hospitalized patients with serious influenza infections was recently authorized by the FDA under Emergency Use Authorization. Unfortunately, resistance to influenza antiviral medications frequently emerges. Indeed, over the past two years the circulating seasonal H1N1 influenza viruses have become widely resistant to oseltamivir, even while other influenza viruses have remained sensitive to the drug. Hence, it is critical to maintain a pipeline of new and improved anti-influenza medications.

In recent years, NIH has been working to develop and test the next generation of influenza antivirals. Three of these drugs are now in clinical testing, including a long-acting neuraminidase inhibitor, an inhibitor of viral replication, and a drug that prevents the virus from entering human lung cells. NIH has begun evaluating how well these candidate antiviral drugs block the 2009 H1N1 strain and screening other compounds for activity against the virus. In this regard, 462 compounds have been tested against the pandemic H1N1 virus, 33 of which showed antiviral activity. NIH intends to conduct clinical trials of antivirals, including new formulations and combinations of licensed drugs and investigational antiviral candidates, in individuals infected with the 2009 H1N1 influenza virus.

Improved methods of diagnosing 2009 H1N1 influenza infection at the point of care would be of substantial value in the months ahead, helping to differentiate people with the new influenza strain from those with other conditions who present with similar symptoms. Prompt and precise point-of-care diagnosis would help to slow the spread of the influenza virus and maximize the efficiency with which stockpiled antivirals are used. NIH has been developing diagnostic platforms capable of rapidly identifying a wide variety of pathogens in clinical samples, including specific subtypes of influenza, and we are now working to accelerate the development of these platforms to provide improved diagnostics for 2009 H1N1 influenza.

**Shared Research Resources**

When infectious diseases emerge, NIH serves an important role in providing research materials, support, and expertise to scientists and to the public health community. These research resources include blood samples from infected patients, immunological assay reagents, animal models, genomic sequencing and information resources, and isolates of the virus.

NIH intramural and extramural researchers, in turn, depend on materials and information shared by CDC, FDA, and other public health agencies around the world. For example, CDC provided NIH intramural investigators and NIH-supported researchers with samples of the 2009 H1N1 virus, while NIH has made available to CDC researchers archived blood samples from people vaccinated against 1976 swine influenza as well as influenza reagents from an NIH research reagent repository. From my perspective, the coordination and cooperation among government agencies, and with academia and private industry, has been outstanding.

**Conclusion**

It is important to recognize that, even months into this worldwide pandemic, we are still only at the earliest stages of understanding how the 2009 H1N1 influenza virus emerged and what impact it might have. Influenza viruses are highly unpredictable, and it is unwise to make predictions about how a virus might behave in the future. For example, although the virus has for the most part

caused moderate influenza symptoms (with important and tragic exceptions), we do not know whether that might change in the coming months. Nor do we know whether the virus will become resistant to the antiviral drugs we have stockpiled. In short, we simply cannot predict at this time whether the 2009 H1N1 pandemic will become more or less severe than we have seen thus far. For these reasons, the NIH and other government agencies have been preparing for any possibility.

The ongoing, collective efforts of HHS, including the NIH, to prepare for an influenza pandemic—with surveillance, research, vaccine manufacturing infrastructure and clinical trials, antiviral drugs, public health measures, effective infection control, and clear public communication—have given us a valuable advantage in responding to the current worldwide pandemic, however it may unfold in the future.

I would be pleased to answer any questions you may have.

Mr. OBEY. Thank you very much. Mr. Bonner, would you introduce our next witness?

Mr. BONNER. I would be happy to, Mr. Chairman. Thank you very much. I am pleased to introduce Dr. Donald Williamson, Alabama Department of Health Officer. He has served as our Public Health Officer since 1992. During that time and before, he has been recognized repeatedly for his public health expertise and for his efforts on behalf of Alabama's children as well as our 4.5 million other citizens and is one of the leading voices on public health. I know today he represents my home State, but he also speaks for his colleagues in the other 49 States.

Like many other members of this committee, Mr. Chairman, I represent a district that includes large rural areas. But unlike some members of the committee, I also represent a city with a large international port and more than 50 miles of coastline. This represents just some of the unique challenges that come to public health officials like Dr. Williamson. He has met those challenges head on and with great success.

Briefly, I would just like to give a tip of the hat to Dr. Williamson. Alabama has been a leader in several areas of public health, especially in the area of All Kids, our State version of SCHIP. It has been one of the most successful programs in the Nation in enrollment as well as in serving eligible children and Dr. Williamson deserves tremendous credit for that.

So, Mr. Chairman, thank you for letting me bring to this committee someone who can talk specifically about how my States our State has helped in coping with the spread of H1N1.

With that, we welcome Dr. Williamson.

Dr. WILLIAMSON. Thank you, Mr. Bonner, for those very kind remarks. Chairman Obey, Ranking Member Tiahrt, and members of the subcommittee, thank you for the opportunity to describe one State's experience with H1N1 2009. Many of the issues with which Alabama has dealt are generalizable to State public health agencies across the Nation.

In my comments I will focus on a few critical components of that response. School began in Alabama in mid-August. Within days of the onset of school we began to observe the spread of influenza illness and H1N1 in our school system. In late, August, of Alabama schools had an absenteeism rate of greater than 5 percent. Fortunately, by late October that percent had declined to 4.5 percent.

The percentage of influenza-like illness in physician offices began to rise shortly after the onset of school and has remained elevated, peaking at 12.3 percent of physician office visits. Currently, 12 percent of emergency room visits are attributable to ILI. Since early September, flu illness accounted for between 3 and 3.8 percent of all hospitalizations. Geographically, Alabama reported widespread inactivity for 9 or 10 consecutive weeks. At this point surveillance suggests that while Alabama has an ongoing outbreak, we have also been monitoring medical care capacity and monitored certain specific indicators. At no time has any bed availability been less than 20 percent.

Both pediatric medical and pediatric ICU bed availability have hovered around 40 percent and current availability approaches 50 percent. Adult capacity has historically been lower. General adult

medicine and adult ICU bed availability has ranged between 20 and 25 percent.

During the early phases of the outbreak, the Department received reports of pharmacists unable to obtain both tamivir and zanamivir in local geographic areas. In addition, we received reports of patients who were indigent or without insurance which paid for antiviral medication. In an effort to address those issues, the Department has provided almost 100,000 courses of antiviral medication through 832 providers.

The antiviral stockpile in Alabama currently appears to be adequate based on our current ongoing burden of disease. As has been observed nationally, there is a strain on the formulary in pediatric preparations. The department formulated a vaccine strategy for Alabama based upon projections of vaccine supply provided to us by the Centers for Disease Control and Prevention.

The estimates provided to the department in late September suggest that Alabama would be able to order approximately 800,000 doses of vaccine by the week ending October 30, 2009. However, new projections of October 23, 2009, show that the amount of vaccine available to Alabama would be reduced to some 400,000 doses available to Alabama prior to the first week of November.

Given this dramatic delay in the release of vaccine, the department was forced to reformulate its vaccine strategy. Instead of focusing vaccination efforts on the broader ACIP categories, the State has chosen to restrict its initial vaccination efforts to the subpriority groups identified by the ACFF.

Likewise, we are now restricting vaccine distribution in the private sector to providers most likely to serve the target sub population, including obstetricians and gynecologists, family practice physicians, and hospitals. In the public sector, to maximize the sites at which these target populations may receive vaccine, we are prioritizing distribution to federally qualified health centers.

Our school-based vaccination efforts originally planned to begin early October or November have been delayed to late November or early December. Current projections show 62 percent of the vaccine coming to Alabama will not be available until after December 1st. Based upon the current distribution schedule and assuming ongoing demand on the target population, it is likely expanding it to all populations of Alabamians who wish to have it may not be possible until late December or early January.

In looking at some things we have learned, it is critical that estimates of vaccine delivery be realistic and credible. States develop their vaccination strategy based upon those estimates. A change in those estimates has a profound ripple effect throughout the public health system. Not only does a change in the available vaccine supply impact the scheduling of the clinic, it also impacts the plans for public information campaign.

Any campaign encouraging expanding vaccination when the supply is limited would likely result in patients becoming disillusioned and frustrated because of their inability to receive the vaccine. In addition, the inability to provide the vaccinations will further undermine the credibility of the public health effort.

Media campaigns must be timed to match the supply of the vaccine. If more vaccine does become available in late November,

media campaigns aimed at encouraging broad scale vaccination have a much greater chance of success and patients a greater chance of being vaccinated.

In summary, while vaccination efforts have begun in Alabama, our long-term vaccination success depends upon the continued interest of individuals in receiving vaccinations in December and January, when vaccine will be more available.

In closing, let me thank this committee. Without the support of this committee, we as a Nation and certainly Alabama as a State would be far less prepared or able to respond.

Thank you again, Mr. Chairman and members of the committee, for this opportunity to share our ongoing experience with H1N1.

[The statement of Dr. Williamson follows:]

TESTIMONY

OF

DONALD E. WILLIAMSON, M.D.

ALABAMA STATE HEALTH OFFICER

TO

THE HOUSE APPROPRIATIONS SUBCOMMITTEE ON LABOR

HEALTH AND HUMAN SERVICES

EDUCATION AND RELATED AGENCIES

NOVEMBER 4, 2009

Thank you for allowing me the opportunity to describe one state's experience with H1N1 2009. Many of the issues with which Alabama has dealt are generalizable to state public health agencies across the nation. I will focus on a few critical components of that response: surveillance, medical care capacity, and vaccine administration.

**Surveillance**

Since attempting to count each individual influenza case is an unproductive and incomplete exercise, Alabama like most states has developed an overlapping surveillance system to provide the most complete picture possible of H1N1 disease. We have established a network of sentinel physicians who report on a weekly basis the percentage of patients seen in their offices who have influenza-like illness (ILI) (fever, cough, or sore throat). Likewise, we have worked with the Alabama Department of Education to monitor school absenteeism over time. Using an information system funded with emergency preparedness dollars and designed initially to assist in tracking hospital capacity during disasters, we have identified the percentage of visits to hospital emergency rooms and the percentage of total admissions to hospitals that are due to ILI. Finally, to ensure an understanding of the circulating viral type, we have implemented a network of physicians who submit samples from ambulatory patients with ILI to the Alabama Department of Public Health Laboratory for PCR identification. In addition, our laboratory surveillance system focuses on samples from hospitalized patients with ILI and pregnant women.

School started in Alabama in mid-August. Within days of the onset of school, we began to observe the spread of ILI and H1N1 disease in our school system. In late August,

53 percent of schools had an absenteeism rate of greater than 5 percent. By late October, the percentage of schools with greater than 5 percent absenteeism had declined to 45 percent. Alabama's baseline for ILI in physician offices has historically been approximately 2.5 percent. The percentage of ILI in physicians' offices began to rise shortly after school began and by early September the percentage of ILI had exceeded 10 percent. Since then, ILI has remained elevated in physicians' offices peaking at 12.3 percent of physician office visits. Currently 9 percent of physician office visits are reported as ILI.

Likewise, elevations in emergency room (ER) visits due to ILI have been observed. In early September, 20 percent of ER visits were attributable to ILI. Currently 12 percent of ER visits are attributable to ILI. Since early September, ILI has accounted for 3.0-3.8 percent of all hospitalizations. Over the past three weeks it has remained constant at 3.0 percent. Surveillance of influenza specimens for viral type demonstrated that 99 percent of positive isolates over the past month are H1N1 2009. Geographically, Alabama has reported widespread influenza activity for nine consecutive weeks. At this point, surveillance suggests that while Alabama has an ongoing influenza outbreak, the magnitude of the outbreak may have peaked.

**Medical Care Capacity**

Utilizing the system which was developed to measure hospital capacity during disasters, we have monitored certain specific indicators of Alabama hospital capacity during the course of the current outbreak. Since early September, we have monitored the

availability of staffed hospital beds, adult ICU beds, pediatric ICU beds, adult medical beds, and pediatric medical beds. At no time has any bed availability been less than 20 percent. Both pediatric medical and pediatric ICU bed availability have hovered around 40 percent and current availability approaches 50 percent. Adult capacity has tended to be lower than pediatric capacity. General adult medicine and adult ICU bed availability has ranged between 20 and 25 percent.

In addition to monitoring medical care availability, we have also assisted with the deployment of antiviral medication. During the early phases of the outbreak, the Department received reports of pharmacists unable to obtain oseltamivir or zanamivir in local geographical areas; in addition, we received reports of patients who were indigent or were without insurance which paid for antiviral medication. In an effort to address temporal geographic shortages, as well as to meet the needs of indigent patients for antiviral medications, the Department created a web portal which allowed pharmacists and physicians to place orders for those medications. As of October 28, 2009, the Department has provided almost 100,000 courses of antiviral medication to 832 providers. The antiviral stockpile appears adequate based on the current burden of disease; however, as has been observed nationally the greatest strain on the formulary is in pediatric preparations.

**VACCINE ADMINISTRATION**

The Department formulated a vaccine administration strategy for Alabama based upon projections of vaccine supply provided to us by the Centers for Disease Control and Prevention. The estimates provided to the Department on September 27, 2009,

projected that Alabama would be able to order 802,938 doses of H1N1 vaccine by the week ending October 30, 2009. Based upon those projections, the Department began a sequential strategy that focused first on allocating vaccine to providers most likely to see the ACIP recommended target population. The next phase of that strategy, expected to begin in late October or early November, was school-based vaccination clinics intended to be completed about Thanksgiving. The final phase, as more vaccine became available, was to provide additional vaccine to private providers, to community vaccinators, such as pharmacies, and to county health departments to hold clinics for individuals in the target population who might not otherwise have been reached. This phase would also enable anyone who wished to reduce their risk of influenza to be vaccinated.

However, based upon projections of October 23, 2009, the amount of vaccine available to be ordered by Alabama prior to the first week of November was reduced from 802,938 to 397,381. Of this, only 276,000 doses were injectable. Given this dramatic delay in the release of vaccine, the Department was forced to reformulate its vaccine strategy. Instead of focusing vaccination efforts on the broader ACIP categories, the state has chosen to restrict its initial vaccination efforts to the subpriority groups identified by the ACIP to include:

- Pregnant women;
- Health care workers;
- Children 6 months of age to 4 years of age;
- Caregivers of children less than 6 months of age;

- Children 5-18 years of age with underlying medical conditions which put them at risk of complications.

Likewise, instead of attempting to provide vaccine to entities who serve the broader priority groups, we are now restricting vaccine distribution in the private sector to providers most likely to serve the target subpopulation. This includes OB/GYNs, pediatricians, family practice physicians, and hospitals. In the public sector to maximize the sites at which these target populations may receive vaccine, we are prioritizing vaccine distribution to federally qualified health centers and to county health departments. Our school-based vaccination efforts have now been delayed until late November or early December. In addition, given the limited amount of vaccine available, initial school vaccination efforts will focus on children less than 10 years of age, a group in need of two vaccinations for maximum protection.

Current projections show that 62 percent of Alabama's vaccine will not be available until after December 1. This is likely to lead to a delay in the provision of vaccine to the broader provider community until December and January. Assuming robust uptake of vaccine by individuals in the subpriority groups, there will be a delay in the expansion of vaccination efforts to the broader ACIP recommended groups. Based upon the current distribution schedule and assuming ongoing demand by the target population, it is likely that expanding the vaccine offering to all Alabamians who wish to reduce their risk of influenza may not be possible until late December or January.

**LESSONS LEARNED**

The most important lesson learned during the H1N1 outbreak is the need for timely and accurate information. The ability to observe the epidemic through multiple data sources (physician office visits, emergency department visits, and school absenteeism) has enabled us to gain a better prospective both of the temporal and geographical movement of the outbreak as well as the likely impact on the health care system. Similarly, it is critical that estimates of vaccine delivery be realistic and credible. States develop their vaccination strategies based on those estimates. A change in those estimates has a profound ripple effect throughout the public health system. Therefore, any changes in vaccine delivery must be communicated immediately and clearly to the states to allow the states maximum opportunity to adjust their plans. Not only does a change in the available vaccine supply impact the scheduling of clinics, it also impacts the plans for public information campaigns. Any mass media campaign encouraging expanded vaccination, when the vaccine supply is so limited, would likely result in patients becoming more frustrated and disillusioned because of their inability to receive vaccine. In addition, the inability to provide the vaccinations will further undermine the credibility of the public health effort. Media campaigns must be timed to match the supply of the vaccine. If vaccine becomes more available in late November, media campaigns aimed at encouraging more broad vaccination have a much greater chance of success and patients have a greater chance of being vaccinated,

In summary, we feel that the surveillance system has provided sufficient information to allow Alabama to understand the magnitude and the severity of H1N1 2009 during the current influenza season. Likewise, while H1N1 has certainly increased health care

demands across the state, at no time has it resulted in critical shortages in any of our monitored resources. The antiviral stockpile has been extremely helpful in meeting needs due to temporal geographic shortages or the need to serve indigent patients. While vaccination efforts have begun in Alabama, the reduced release of vaccine forced the state to develop an alternative strategy. The lack of vaccine significantly limits the number of individuals we can currently vaccinate. Our long term vaccination success depends upon the continued interest of individuals in receiving vaccinations in December and January when vaccine will be more available.

Again, thank you Mr. Chairman and members of the committee for this opportunity to share our ongoing experience with H1N1 2009.

Mr. OBEY. Ms. McCollum, would you introduce our next witness?

Ms. MCCOLLUM. Thank you for the opportunity to introduce a person I know well, I consider a friend, Rob Fulton. He has been the Director of the St. Paul—Ramsey County Department of Public Health since 1988 and the Labor Health and Human Services Education member. He is here to brief us on H1N1.

Rob directs an operation of large, full-service public health entity focusing on communicating communicable diseases, promoting the health in children, youth and their families, protecting the environment, reducing environmental health hazards, reducing chronic disease, and assuring emergency preparedness. He does this in many languages. One of the largest hospitals in Ramsey County has on hand people to interpret up to 47 different languages.

He is the treasurer of the local public health association in Minnesota, Vice Chair of the Minnesota Block Grant Advisory Committee. He is also very active and serves on the committees of the Greater United Way. He is a school board member.

The reason why I bring all this up, Mr. Chair, is he is not only a person who is an expert on public health and reaching out to the community, he is a person actively engaged in the community and does hear from them directly firsthand when they are fearful of something and when they have questions.

Mr. Chairman, I present you Rob Fulton.

Mr. FULTON. Thank you, Mr. Chairman, Mr. Tiahrt, members of the subcommittee. Ramsey County, Minnesota, has a diverse population. St. Paul—Ramsey Public Health Department has a number of specialty clinics that we operate for TB, STDs, family planning, and women's health, as well as a large family home visiting program with over 100 families a year. We have 32 on staff that provide these services.

We have been planning for a pandemic since the late 1990s. Federal funding to support our planning came shortly after the 9/11 event and then the October 2001 anthrax, which I am sure you are all very familiar with.

The investment that the Federal Government has made in public health emergency planning and especially in the recent public health emergency response funding has been vital assistance to us in dealing with this current situation.

In late April this year is when H1N1 first reached our community. One of the biggest tasks we faced was getting accurate and timely information for our community about the threat of H1N1. We immediately began providing the mitigation information to residents of the county on how to avoid getting sick—wash your hands, cover your cough, stay home if you are sick. The same messages we gave in the 1918 pandemic are still the most effective messages today. As the H1N1 returned this fall, it is important we continue these messages until we can begin to vaccinate our residents.

One important aspect of this communication is how to reach the many limited English-proficient members of our community. Our department, along with other local public health departments, initiated a service called Emergency Community Health Outreach, or ECHO. This nonprofit organization produces monthly health shows on our local public health television in six different languages.

They also have telephone message lines in different languages and Web site with information.

A second major effort at the local level was to assure that as many of the appropriate clinics in Ramsey County as possible applied to receive H1N1 vaccine. While we have large system clinics among the 218 clinics we also have 63 affiliated clinics, including our three federally qualified health centers, health care for the homeless clinics, and five school districts.

As the H1N1 vaccine became available to us in small amounts, our local public health department took on the responsibility of seeing that emergency medical service and other first responders not attached to hospitals receive vaccine. One of the dilemmas was that the initial vaccine provided to us by the State was the weakened live virus, and this type of vaccine has some limitations.

We have also become the distributor of antiviral drugs. Minnesota has established a flu line that can help to diagnosis flu symptoms over the phone and prescribe antivirals to those persons who can best use them. For those whose health insurance does not cover prescriptions, the prescriptions are sent to our department and for the time these people can come and get the antivirals without cost. We are also the local stockpile of these antivirals that will distribute to our local clinics as they need them.

Another responsibility for local public health is to be the repository and distributor of personal protective equipment, such as masks and N95 respirators. These supplies are coming from the strategic national stockpile that was distributed in part to the State last spring.

So how do we do all this at the local level? We set up our incident command system last spring and reinitiated the system 4 weeks ago. This is the formal system of managing emergency situations that we trained and exercised for the past 8 years. As of today, we have 135 of our 320 employees that have been assigned to some duties for the situation.

The challenge for public health is that these folks have to give up doing their regular work in order to meet the needs of the H1N1 pandemic. We do have some concerns. Obviously, the delays in delivery of H1N1 vaccine are causing disruptions to our plans to vaccinate as many persons as possible as quickly as possible.

We are seeing an increasing number of illnesses in our community and hospitalizations, and we still have limited supplies of vaccine. We know that the credibility of the entire public health system is in question due to the slow arrival of the H1N1 vaccine. The demand for this vaccine is high right now, but slow in arriving. This demand may wane. For example, we are anticipating some 7,800 doses of vaccine to focus on school children 9 and under.

Our challenge is to distribute and vaccinate in a fair manner so we cannot meet what will be the high demand for vaccine in children.

Another issue is the delay in the delivery of seasonal flu vaccine. While this is not an immediate problem, it could become one if we don't see adequate supplies of seasonal vaccine by December. Minnesota is proud that we have the highest rates of seasonal flu vaccination for persons over 65 in this country. But this will be more challenging to accomplish if the delays continue.

We anticipate that we will be in the incident command system operations well into 2010. This will have a real impact on the delivery of other important services. For example, we are planning to move many of our home visiting services from weekly visits to biweekly visits. We are also planning to reduce the frequency of our food beverage and lodging inspections, and we are very concerned that should we have another emergency, such as a large scale foodborne outbreak or a tuberculosis outbreak that will require diverting our staff that we will have problems covering that.

As you know, local and State funding for public health has been impacted by the poor economy, and we just eliminated 5 percent of our staff to meet 2010 budget goals. Wellness funding that is now in the health care reform bill is critical to assuring a strong local public health infrastructure for the future.

In summary, local public health in the midst of the H1N1 pandemic finds itself wearing many different hats. Many of the jobs we are asked to do are familiar tasks, but some are not. Local public health workers are putting in long hours and deeply committed to serving our communities.

Thank you.

[The statement of Mr. Fulton follows:]

TESTIMONY OF ROB FULTON, DIRECTOR OF PUBLIC HEALTH

SAINT PAUL – RAMSEY COUNTY DEPARTMENT OF PUBLIC HEALTH, SAINT PAUL, MN

MEMBER BRIEFING: LABOR, HHS, EDCUCATION SUBCOMMITTEE

NOVEMBER 4, 2009

My name is Rob Fulton and I'm the director of the Saint Paul – Ramsey County Department of Public Health. Ramsey County, MN is an urban county with a population of 517,000. Saint Paul, the capitol of Minnesota is the largest of the 17 cities in the county. Ramsey County has a diverse population with the highest poverty rate of any county in Minnesota. Saint Paul – Ramsey Public Health is a full service department providing specialty clinic services for TB, STDs, family planning and women's health as well as a large family home visiting program serving 1900 families a year. Our WIC program sees 19,500 women and children each month. We also provide environmental health services, solid waste management, correctional health, and community health promotion services. We have 320 staff to provide these services and budget in excess of $52M.

We have been planning for a pandemic since the late 1990s. Federal funding to support our planning came shortly after the 9/11/01 event and the October, 2001 anthrax event. For example we developed a department initiative in partnership with John Hopkins School of Public Health called the "Roadmap to Preparedness" in which we committed to train as many of our staff as possible in emergency management systems and their potential resource roles in a public health emergency. We have used the resources of FEMA and their training courses and training events. For example, in fulfilling our obligation under the Public Health Emergency Planning funds, we conducted an exercise simulating a mass vaccination clinic on September 29 that involved more than 450 staff and volunteers.

The investment that the federal government has made in public health emergency planning and especially in the recent Public Health Emergency Response funding has been vital assistance to us in dealing with the current situation. I can assure you that local public health is well trained and ready to be the ground troops in dealing with H1N1 pandemic.

In late April of this year, when H1N1 first reached our community, one of the biggest tasks we faced was getting accurate and timely information to our community about the threat of H1N1. We immediately began providing the mitigation information to the residents of our county on how to avoid getting sick. Wash your hands, cover your cough, and stay home if you are sick, the same messages we gave in the 1918 pandemic are still the most effective messages today.

As the H1N1 flu returned this fall, it was important that we continue these messages until we could begin to vaccinate our residents. One important aspect of this communication is how to reach the many limited English proficient members of our community. Our department along with other local public health departments initiated a service called Emergency Community Health Outreach or ECHO. This now non-profit organization produces monthly health shows on our local public televising in six different languages. They also have message lines in 12 different languages and a website with information in the same 12 languages.

The second major effort was to assure that as many of the appropriate clinics in Ramsey County applied to receive H1N1 vaccine. While we have large system clinics among our 218 clinics, we also have 63 unaffiliated clinics including our three Federally Qualified Health Centers, our Health Care for the Homeless clinics., five school districts and nine colleges with health services. A number of these clinics, such as obstetrical specialties and college health services don't routinely participate in the dispensing of vaccinations and needed our help to participate in the distribution system for H1N1 vaccine.

The Minnesota Department of Health has an excellent surveillance system and we use their information in our planning and tactical operations. However, it is the local public health systems responsibility to see that accurate information is provided to at risk populations, the general public, health care clinics, our elected officials and other partner agencies both inside and outside the county. We have done this by developing a variety of community pieces and enlisting our staff and community partners to get the word out on H1N1. Our community health promotion activities also include a website that is updated as often as daily, social media such as Twitter and an H1N1 blog, messaging to our community partners, and being accessible to the media to present current and accurate information.

As H1N1 vaccine became available, to us in small amounts our local public health department took on the responsibility of seeing that emergency medical service and other first responders not attached to hospitals received vaccine. One of the dilemmas was that the initial vaccine provided to us by the state was the weakened live virus vaccine commonly called flumist. This type of vaccine has some limitation such as maximum age. We uncovered some resistance in some of the first responders to receiving live virus. We conducted six vaccination clinics using our staff in both day and evening times in the past ten days to reach first responders. We also received a small amount of injectable vaccine and, along with the remaining live virus vaccine' have distributed this to many of the unaffiliated clinics in the county this past Friday and Monday. Our focus was on getting vaccine to those clinics that served high numbers of priority vaccination groups such as pregnant women and young children.

We have also become the distributor of anti-viral drugs. Minnesota has established a flu line that can help to diagnose flu symptoms and prescribe anti-virals to those persons who can best

use them. For persons who are uninsured or for those whose health insurance does not cover prescriptions, the prescriptions are sent to our department and these people can come and get the anti-virals without cost. We are also a local stockpile of these anti-virals that we will distribute to our local clinics as they need them. Another responsibility for local public health is to be the depository and distributor of personal protective equipment such as masks and respirators. These supplies are coming from the Strategic National Stockpile that was distributed in part to the state last spring.

So how do we do all of this? We set up our Incident command system last spring and reinitiated this system four weeks ago. This is the formal system of managing emergency situations that we have trained and exercised for over the past eight years. As of today, we have 135 of our 320 employees that have been assigned some duties for this situation. The challenge for local public health is that these folks have to give up doing their regular work in order to meet the needs of the H1N1 pandemic. We are preparing to initiate our Continuity of Operation Plan and determine what services we will suspend until this situation is over. Our county has a detailed COOP plan for dealing with a flu event and we are surveying the amount of sick leave that is being used by our staff.

We do have some concerns. The delays in delivery of H1N1 vaccine are causing disruptions to our plans to vaccinate as many persons as possible as quickly as possible. We are seeing increasing number of illness and hospitalizations and still have very limited supplies of vaccine. We know that the credibility of the entire public health system is in question due to the slow arrival of H1N1 vaccine. The demand for H1N1 vaccine is high right now. If it is slow in arriving, this demand may wane. We are anticipating some 7800 doses of vaccine to focus on school children 9 and under. Yet, we have over 20,000 children in this age category in schools. Our challenge is to distribute and vaccinate in a fair manner. So, we cannot meet what will be the high demand for vaccine in children.

Another issue is the delay in the delivery of seasonal flu vaccine. While this is not an immediate problem, it could become one if we don't see adequate supplies of seasonal vaccine by early December. Minnesota is proud that we have the highest rates of seasonal flu vaccination for persons over 65 in the country, but this will be more challenging to accomplish if the delays continue.

We are anticipating that we will be in the incident command system operations well into 2010. This will have a real impact on the delivery of our other important services. For example, we are planning to move from weekly to biweekly visits in our family home visiting program. We may also be reducing the frequency of our food, beverage, and lodging inspections as these staff are called up for duties in our command structure. We are very concerned should we have another emergency event such as a large scale food borne outbreak or a tuberculosis

outbreak that requires diverting staff. Local and state funding for public health has been impacted by the poor economy and we have just eliminated 5% of our staff to meet our 2010 budget goals. Wellness funding and family home visiting funding in the health care reform legislation will be very helpful to us.

In summary, local public health in the midst of the H1N1 pandemic, finds itself wearing many different hats. Many of the jobs we are asked to do are familiar tasks, but some are not. Local public health workers are putting in long hours and deeply committed to serving our communities. We are well trained, prepared, and willing to meet the many challenges that we are facing with H1N1 flu pandemic.

Mr. TIAHRT. Mr. Chairman, one of the things that comes up in the testimony that I think very important to how we direct our questions is the timeline to develop the vaccine. We notice that they had to make a selection of the virus and certain steps they go through, and when you have a shortage you kind of want to know how long it is going to take to get the vaccine. Perhaps somebody can explain the timeline.

Mr. OBEY. I think we will get to that. The way I want to proceed first is to provide an opportunity for both the majority and minority staff to ask the more technical and exacting questions, and then we can move to any questions that the members might have. We will start with the majority first for about 20 minutes.

H1N1 VACCINE ESTIMATES

MAJORITY STAFF. Good morning. I want to first talk about the H1N1 vaccine shortages that Dr. Williamson and Mr. Fulton outlined as their problems in the State and local areas. HHS's key goal for vaccine preparedness under the HHS pandemic plan was to develop sufficient domestic manufacturing capacity to produce pandemic vaccine for the entire U.S. population of 300 million persons within 6 months of pandemic onset.

While HHS, particularly BARDA and CDC, have worked 24/7 to address the H1N1 pandemic, we are falling miserably short of this goal. Following the H1N1 outbreak last spring, the Federal Government contracted with its five suppliers of seasonal flu vaccine to deliver 250 million doses of H1N1 vaccine to protect the U.S. population from the spread of the virus in the fall. Initial government estimates indicated that 160 million doses of the H1N1 vaccine would be available by October.

Based on information provided by the vaccine manufacturers, HHS later revised this estimate downward to roughly 40 million doses. By the end of October—on October 29—CDC reported that 24.8 million doses had been made available, still short of the lower estimate of 40 million. HHS's data supplied to the committee staff indicate that doses sufficient to cover all priority populations will likely not be available until January 2010.

Is that correct?

Dr. FRIEDEN. As you point out, there has been a steady downgrading of the number of vaccine doses that will be available. That number has continued to decrease through the summer and into September and October. As of today, there are 32.3 million doses available. At this point we are focused on going week to week in terms of what we are anticipating coming to us.

What we focus on at CDC is ensuring we can receive the vaccine 7 days a week, provide for overnight shipping and facilitating States' vaccine distribution, so we can get it into doctors' offices and patients as quickly as possible.

H1N1 VACCINE DELIVERY

MAJORITY STAFF. Isn't that a concern that some of the high risk persons such as pregnant women and young children may have to wait several months to get the vaccine?

Dr. FRIEDEN. We are very frustrated on the vaccine delivery. As we said in the opening remarks, we are stuck with techniques

which we are very confident in the safety of but which take too long. The initial estimates were that after the emergence of a new strain, it would take 6 to 9 months for a vaccine to become available.

If you look at the previous pandemics, vaccine production has not made it possible to have vaccine available for the first wave of the disease.

We have a flu season that lasts until May. Dr. Lurie can discuss in more detail the work with the manufacturers to try everything possible to get more vaccine.

MAJORITY STAFF. When do you anticipate there will be enough vaccine to cover the priority population?

Dr. FRIEDEN. As I said, at this point, from CDC's standpoint, we are focusing one week at a time. We already have been burned, quite frankly, by projections that have not come to pass. Our goal now is to get the vaccine out as rapidly as possible and then to ensure that it is available and used by the priority patients.

Mr. OBEY. Mr. Tiahrt raised a question. I understand you are shy about making predictions. Nonetheless, you must have some observations based on your experience to lead you to have some estimate of a timeline.

Dr. LURIE. Maybe I can jump in here, if I can. We have been working extremely hard with each of the manufacturers to be sure that all of the stumbling blocks that we have any control of and that they have control of are really out of the way. Some of the problems that they encountered early on in terms of growth, in terms of filling capacity, et cetera, seem to have been very well addressed. But, to be quite honest, as I think you heard from the beginning, and as we know from history, the flu is really unpredictable.

I think we are pretty hesitant about projecting forward more than week to week, largely because anything could happen. So while I think at this point we feel like more vaccine is coming out every week. At this point creating sort of more expectation, I think, will be more confusing than anything else.

MAJORITY STAFF. What have you learned on the site visits? Why can't more vaccine be produced by the end of the year? I think it goes to the timeline of the vaccine and production.

Dr. LURIE. On the site visits what we have done is a couple of things. I brought along a graphic which sort of might help a little bit to explain things. But at this point the manufacturers really are where they are with their production—let me just pass this out to the committee.

The manufacturers, I think, have all made a lot of progress with their yield and their growth, which is—the first step is really sort of growing this virus. So what this really tries to depict is the manufacturing process in some sense, as Mr. Tiahrt asked, and where we have made investments, that is the stuff in green.

The stuff that I know you are most interested in is down the left-hand column in yellow.

So the first problem that everybody really encountered was poor virus growth.

So the yields of virus, and so the yield of vaccine, continued to decrease throughout the summer and into the early fall. All of the

manufacturers have told us now that those are—they are really through those, at least for now. Again, something could happen that could stunt that virus growth, and that is one of the reasons that we are hesitant to predict.

One of the things that we did on the site visits was really to look at the production challenges and to try to see if we could work together to figure out were there other production challenges that together we could overcome. If one manufacturer didn't have enough filling capacity, for example, we could potentially help identify a source for them to fill in a contract manufacturer that was licensed in the United States. And we have done those things. We have shifted all of the vaccine manufacturing, to the extent we can, to multidose vials first because they are faster to fill, leaving the rest left over, as I know you have been interested in, for the single-dose syringes.

So we have really worked with them to shift everything they can do to get vaccine out as fast as they possibly can. And then lot by lot we are tracking through the process so that to the degree even that when a lot is ready to be released at a manufacturer, we actually have a truck waiting and pulled up at the loading dock ready to accept that vaccine and bring it to the distribution site.

So we have been working sort of at every step of the process to get any delays out. That is what those site visits have largely been about.

VACCINE MANUFACTURERS

MAJORITY STAFF. I have a question about the contracts. HHS purchased enough vaccine to produce 251 million doses, but has only contracted with manufacturers to finish 117 million doses. Why hasn't HHS contracted to fill 251 million doses?

Dr. LURIE. As you know, we need to really have a balance between being sure we have got enough vaccine throughout the time that people need and want it and being careful stewards of society's resources here. So the biggest issue first is to get that bulk vaccine produced. It takes 4 to 6 weeks from when you have that bulk vaccine to do what is called fill and finish—put it in vials, sterility test it, to have it safe for release and ready for distribution. And so we have gone ahead, as you said, and issued orders for the first 117 million to be put into vials and actually this week are issuing more orders for additional vaccine so that we don't have a gap. Because of the delays in vaccine, that 117 million is taking us further into the year than we thought it would.

We will continue to issue additional task orders in time to fill and finish vaccines so that there is no gap in the delivery.

On the other hand, we don't want at the very end of this to be sitting with a lot of vaccine already in vials that can't be used. It is better to keep it in its bulk form so that it could be used, for example, in the seasonal campaign next year or potentially available to adjuvant for the developing world.

But please be assured that we have a very steady stream of filled and finished product coming out of the pipeline, and we are buying it as fast as the manufacturers can produce it.

VACCINE TECHNOLOGY

MAJORITY STAFF. Next I want to ask some questions about the vaccine technology. Everybody has alluded to the fact that we are using 1950s-era technology to produce a vaccine. European countries, though, have already approved and licensed cell-based vaccine technology and are benefiting from that faster technology in this pandemic. As we understand the cell-based method, it doesn't take as long to produce a seed strain. It allows for a more reliable and sterile method of replicating the vaccine in cells rather than chicken eggs. It has the added benefit of allowing the vaccine to be provided to people with egg allergies, and it can be made at least four weeks faster and in greater volumes than egg-based vaccine.

HHS has invested over $1,400,000,000 for research and development and in new facilities to produce the cell-based vaccine. Six manufacturers have received contracts for this work, and one manufacturer, Novartis, is building a facility in North Carolina. Yet it appears that licensed cell-based vaccine in the U.S. is still at least three years away.

When might these new facilities obtain approval from FDA to begin manufacturing? What actions can HHS take to expedite this process?

Dr. LURIE. Let me say first that we are very encouraged both by the development of cell-based technologies and other new technologies, I think, that are coming down the line, and that we have invested in both from the basic science perspective from Dr. Fauci's end and through advanced development through the BARDA end. The first cell-based manufacturing facility is now being built in Holly Springs, North Carolina, by Novartis, and we have provided substantial funding to help with that facility, and so that we will have capacity there to manufacture cell-based vaccine when it is available for manufacturing.

Our understanding is that right now that manufacturing facility will first be available to manufacture flu vaccine, again, if all goes according to plan, in 2011. When the vaccine will be licensed is really an issue of when the company is ready with the techniques, with the manufacturing, when the material is submitted to FDA, et cetera. So I cannot speak to when the FDA would approve a license.

CELL-BASED TECHNOLOGIES

MAJORITY STAFF. What impact would cell-based vaccine really have on the production capacity and manufacturing time?

Dr. LURIE. Well, as you already said, we believe that cell-based technologies will get us vaccine faster, more reliably. We will avoid the problems with egg-based allergies, as you said, and I think we are very, very encouraged by that.

I want to point out that, as you alluded to and as Members have alluded to, we need this manufacturing capacity in the United States. This cell-based facility is the first one. It is going to get us maybe a little shy of halfway to what our pandemic goal might be in terms of capacity to make vaccine for the entire United States. So while we are really excited about this step forward, we need to continue to invest in cell-based technologies, and in additional

manufacturing facilities, and additional new technologies to take us even further into the 21st century, and to then be able to take those technologies to scale in large-scale manufacturing in the United States.

Dr. FAUCI. Could I just add to that so there is no confusion about the relationship between cell-based technologies and other technologies that don't require the virus to grow?

So it is entirely conceivable that you could have a cell-based technology that requires the virus to grow, and it will grow very poorly in the cells. So when you have to get the virus to grow, there is no guarantee that you are going to all of a sudden get away from all of the vicissitudes of egg-based.

Probably more important than being more quick or quicker, like 3, 4 weeks, whatever, is the surge capacity of cell-based, so you can get all of these vats of cells ready to go, and when you need to make more, you just pull a vat out and start growing it. We feel that the answer to these kinds of uncertainty is to do the kinds of platforms that we are doing, basic research, clinical research and partnering with the biotech companies to take vaccinology from influenza into the 21st century by not requiring the virus to grow.

There are so many of those different techniques. One of them is, for example, to take the DNA that codes for the hemagglutinin, which is the important component of the immunogenicity of this, and inject it into an individual and have that person make a lot of immune response against that hemagglutinin. You don't have to require the virus to grow anywhere. You could just make that DNA and make it in unlimited amounts.

Those are the kinds of technology. There are about five or six platforms. So, although cell-based is important and that is the next step, which we are pushing for and have invested a lot of money in, that is not the endgame for us. The endgame is to get away from requiring the virus to grow.

Thank you.

### COST OF NEW TECHNOLOGIES

MAJORITY STAFF. Will vaccines using either cell-based or any of these new technologies be more expensive? And if so, how will this affect both seasonal and pandemic flu prevention campaigns on a Federal and State level?

Dr. LURIE. That is a great question. I am not sure at this point that I am able to answer whether they will be more expensive. Certainly there is a lot of investment in research and development that goes into making and producing any vaccine, and certainly the more of it you make, and the more of it you use, the lower the price gets, because you have all those efficiencies of scale. But I don't think I could predict that now.

Dr. FAUCI. In general, new technologies, when they start off, turn out to be more expensive than molecular—as you scale up and really get a lot going, and you get a predictability about how much you can order, the prices plummet. But right from the get-go, if you are starting with a new technology that is going to maybe take 10 or 15 percent of the vaccine requirement, that technology you can almost guarantee is going to be more expensive initially and then ultimately would become much less expensive.

MAJORITY STAFF. Had HHS invested solely in bringing on and approving new technologies rather than focusing considerable resources on egg-based vaccine, would we have had this newer, faster and more reliable method for the H1N1 pandemic?

Dr. LURIE. Hindsight is always a good thing, and I will confess that I don't have the hindsight to be able to answer that question. Things always take longer than they should have. And I can remember we first started talking about the need to get away from egg-based technologies probably in the late 1990s, and we invested—started investing very heavily in the science at that point, largely under Dr. Fauci's leadership, to move to both a cell-based and some of the newer technologies that he alluded to. You have to have those platforms ready and the techniques ready before you can even start to invest in the manufacturing facility and take it to scale.

Having said that, yes, we could have invested more, and, yes, we could continue to invest more in the advanced development of all of these new techniques and new vaccines. And I believe that we need to continue to do that.

Mr. OBEY. I am going to interrupt because I am informed that we are going to have some votes in about 10 minutes on the House floor. I would like to give the Minority an opportunity to proceed at this time if we can.

Mr. Tiahrt, how do you want to proceed?

ISOLATING FLU VIRUS

Mr. TIAHRT. There are a couple of questions that would help lay the ground rules of some further questioning, and like the time line of how much is available, and so maybe it is a projection, and I think that might be helpful.

I will just refer back to your chart, if that is okay with you. I was a little curious about on the right-hand side, there looks like there is a pallet coming down from the side, and I really couldn't connect that to what was going on. Do we have to airdrop this in or——

Dr. LURIE. I wish we could.

Mr. TIAHRT. Click your heels, and we will get her home.

Dr. LURIE. They look a little orange, too, but not quite like the red shoes I have on.

So what that is really intended to convey—first of all, as we all know right now, we are still dependent on growing vaccine in eggs.

Mr. TIAHRT. Was that a pallet of eggs?

Dr. LURIE. That is a pallet of eggs, and what this is intended to show is that until we have these new technologies, we have had to invest in maintaining a steady supply of millions and millions of eggs.

Mr. TIAHRT. It says here we have started the egg supply contract in 2004. And so how many eggs do you need? Is there one vaccine per egg, or is it multiple eggs that are required?

Dr. LURIE. So one of the challenges as I think during seasonal flu vaccine—and my colleagues can correct me if I am a little bit off here—but you can get at least two, sometimes more, sometimes three doses of vaccine per egg. But each virus grows at a different rate. For this H1N1, I think when people started with the very

first strains, they were getting about .2, .3 doses per egg. And they have done a lot of work to change the strain.

Mr. TIAHRT. Will it increase the capacity?

Dr. LURIE. To increase that capacity. But you need millions of eggs is the answer.

Mr. TIAHRT. Okay. Do we have millions of eggs now?

Dr. LURIE. We have millions of eggs now, and we have been securing millions of eggs and millions of chickens. I learned when I came to this job that I was responsible for many chicken farms. So absolutely.

Mr. TIAHRT. Well, so if you are going to look at a time line, and you need to increase the dosage, you start with what? You start with ordering eggs or buying chickens?

Dr. LURIE. So what you have to do in the time line is you have to do a couple of things simultaneously. You have to have the eggs, and, you know, they have to be fertilized and embryonated eggs, and at the same time——

Mr. TIAHRT. But you don't go to the store to get them. It takes a while to order them?

Dr. LURIE. We have a steady supply and a steady order now, so that is not the hang-up, and that is because of investments made in 2004. Okay? But then when a new strain comes along, what you have to do is isolate the virus, get the seed strain, as Dr. Fauci alluded to in his graphic, and then it has to grow so that you can actually inoculate the eggs.

Mr. TIAHRT. How long does it take to isolate a virus? Is there an average time, or is there a unique time?

Dr. FRIEDEN. Just days. In fact, this virus was isolated in California by CDC work that was ongoing to identify new strains before the Mexican outbreak.

Mr. TIAHRT. So they are constantly looking for a mutation to this——

Dr. FRIEDEN. Within the resource limitations that we have, yes.

Mr. TIAHRT. Okay. So once we capture that, then how do they grow enough to put into the eggs? How long does that take?

Dr. FRIEDEN. The first step is that CDC will isolate the virus, select a candidate strain that looks like it will be good for a vaccine, and send that to partner institutions that will then change it to a form that facilitates the making of vaccine.

It took us literally days to get that done after isolating the virus. We provided it to partners. The partners then provide it openly to manufacturers, academic institutions, governments throughout the country and around the world.

TIME LINE FOR VIRUS ISOLATION

Mr. TIAHRT. So from the time you isolate the virus until you inoculate the eggs is how long?

Dr. LURIE. What we are hearing is about 10 days, 2 weeks.

Dr. FAUCI. It really varies because there are two ways to get—you have to get what is called the seed virus and a reference strain. And what happens is that there are two ways to do that. You have viruses that are very good growers and adaptive to eggs, a Puerto Rico strain.

Mr. TIAHRT. What is the longest it would take then?

Dr. FAUCI. Well, it could take several weeks. It could take a month if you don't get a good reference strain or a seed virus. If you do it real quick, and you are lucky, you could do it days to a couple of weeks. If it takes a long time, you could go a month.

Mr. TIAHRT. So if you were going to get 100,000 vaccines, it would take 2 to 4 weeks to get ready to inoculate the eggs, and then how long for it to incubate within the eggs?

Dr. FAUCI. That takes months and months. And again, that depends on how quickly it grows. So if you have isolation within a few days, you get that, it takes a few weeks to get the reference strain or the seed virus. You grow it up, you give to the different companies, and they start adapting it to their egg system or whatever system they use. If it hits the ground running and it is really a good grower, you could start making that right away and getting yields within a period of a couple of months. Getting the yield for what you want, the whole process generally——

Mr. TIAHRT. Let us just use 100,000 as kind of a benchmark, 100,000 vaccines. You want to end up with 100,000 vials—is that the correct term?

Dr. FAUCI. Yeah.

Mr. TIAHRT. I am just trying to get my arms around what is the—how long can we expect this process to last or to take? And it seems kind of nebulous now. I can't project forward. And if I needed 100,000 vaccines at some point in time, when would I expect those to be available? When you order a product, it has a delivery date. What is the delivery date for 100,000 vials?

Dr. FAUCI. Planning for the pandemic, it is always 6 to 9 months. So from the day the virus is identified to the day a vaccine is ready, then you give to the patient.

Dr. FAUCI. But 100,000 is really a small amount of vaccine. So if you look at—yeah.

Mr. TIAHRT. The time line, what is a realistic time line?

Dr. FAUCI. If it is a real fast grower, you could knock 100,000 off in a few days actually if you have a big enough plant. But I think that the important issue to understand is that on a regular flu year where you have a reasonably good grower, no glitches, from the time you isolate the virus or make the decision of what you are going to put in your vaccine to the time you get it in the vial ranges from 6 to 9 months, 6 to 8 months. That is the time line.

TIMEFRAME FOR H1N1 INFLUENZA VACCINE

Mr. TIAHRT. We can expect the same for the H1N1?

Dr. FAUCI. We had hoped that that was the case, and there were a couple of issues, I think three issues. And I believe that was the question you asked right from the beginning that you wanted to get to.

So if you look at the timeframe, when you decide what you are going to do with seasonal vaccine, you usually make your decision around January, and you start this process. If it is a reasonably good grower, you get what you need around the middle of the summer. You start getting it ready to send out in September. You get it out to the people who need it, and then the flu season doesn't really hit you in earnest until the end of the fall, the beginning of the winter and well into the winter. So now what you have here

is a process that started in April. So right away the wiggle room for slow growth, you have one foot on a banana peel there because you have lost 3 months.

On the other end of the spectrum, instead of having some cushion room for a flu season to start, the virus never left in the summer, and it was just waiting for the kids to come back to school at the end of August and the beginning of September. So instead of having the grace period of things really happening in earnest in December and January, they happened in earnest at the end of August and the beginning of September. Superimpose upon that a virus that doesn't really grow very well, and you have a triple whammy. You start late through no fault of anybody. That is when the virus appeared. You have a flu waiting for you when the kids go back to school, and you have a slow grower. That is the issue. That is the issue.

Mr. TIAHRT. So we have 6 to 9 months, which, to me, if you don't have a time line, and there is all of this sort of I guess I will use the term slush in the schedule, and it is kind of slushy, then I am not sure we can properly manage it, because you can say, oh, well, it is going to take longer than we expected, and so that is just the way it is. I want to make sure that we are managing this from our perspective as the government. I mean, we took over General Motors in a couple of days, we took over the banking industry in a couple of weeks, so why can't we take over this process and get it to work right in a time line that is not 50 percent off, you know, 3 months one way or the other?

Dr. FAUCI. That is a superb question, and it is the question that is frustrating us all, because the thing that really is—at this point in time with this technology which is being used, for which there was no choice but to use it because it was the only available technology, for this type of technology, as difficult as it is—and we swallow hard when we say it—you really can't do anything when you have a virus that is not growing well except trying to wiggle it around to get it to grow better. So you really can't say, well, now we definitely are going to have these amount of doses, which is the reason why Dr. Lurie has said it is very difficult now when you have such a fragile system to make an absolute definitive prediction.

Mr. TIAHRT. And we are talking about the American capacity, correct? I mean, we are relying on worldwide production for this. And so how much less control do we have over the worldwide production of this? I mean, we are talking about 6 to 9 months for domestic capacity, and does that—or does that include the ability for Australia, which we contracted with, and then they diverted their supply for Australia, not a surprise. So we have limited capacity here, and we have this sort of slush in the schedule, does that apply to worldwide, or is it worse overseas like with the interruption of Australian production?

Dr. FAUCI. Everybody has the same problem with growing this virus. This is a global issue. This is a global issue. This is not something that is peculiar to the United States.

Mr. OBEY. Would the gentleman yield?

Mr. TIAHRT. Yes.

PREPARATION OF THIMEROSAL-FREE VACCINE

Mr. OBEY. I would like to add one more complicating factor to this. As we know, we have had a controversy involving thimerosal. As I understand it, the prepared doses that were thimerosal-free took considerably longer to produce the same compound—has that controversy, in your judgment, added appreciably to the time it has taken to get this off the ground?

Dr. FAUCI. I think a bit, but not substantially. That is not the major issue. That is not the major issue.

Mr. OBEY. I mean, if it takes so much longer to prepare the doses, but not the thimerosal-free, then why does that take—why is that not——

Dr. FAUCI. If you have multidose vials that would require having a preservative like thimerosal, it facilitates the process rather than having to put single—but I don't think that is the answer to the problem. The answer to the problem is the fundamental terrible growth of this virus earlier.

Dr. LURIE. Thimerosal is not involved in whether the virus grows or not. Thimerosal is added at the end to those multidose vials as a preservative. So if the major problem is whether the virus grows and whether you get to those big vats of vaccine that is ready to get put in vials, thimerosal has no effect on that.

Mr. TIAHRT. If the growth time is slow, then why do we have a pandemic?

Dr. FRIEDEN. There is a difference between how it grows in the laboratory and how it spreads from person to person. One of the reasons that this virus has spread so rapidly and affects younger people more is that it is unfamiliar to us. So there hasn't been a similar virus circulating widely in decades, and that means that it can spread rapidly among people who don't have any immunity from having been exposed to similar viruses in the past.

Mr. TIAHRT. So it is the strain that is unusual to our younger population now that allows this to grow so freely among kids under 5. I guess that is the—what do we call that group, the risk or priority population? What is the priority population? Is it children that are 5 and pregnant women?

Dr. FRIEDEN. There are five groups that are a priority for vaccination. One is health care workers who care for people with influenza and need to be protected. The second is pregnant women, who are at higher risk. The third is people who care for infants 6 months or younger, because we don't give vaccine to infants 6 months or younger, so we protect them by protecting the people around them. The fourth is kids and young adults from 6 months to 24 years of age more likely to get the illness. And then the fifth is people 25 to 64 who have underlying health conditions, and if they get the flu, they are more likely to become severely ill.

Mr. OBEY. Let me interrupt and say that we have got four minutes left on the clock to vote. So what I would like to do is get in one other person's round of questions before we break to vote.

Ms. Roybal-Allard.

VACCINE AVAILABILITY

Ms. ROYBAL-ALLARD. Thank you, Mr. Chairman, for having this important hearing.

I want to go back to the shortage issue. There have been news media reports of people standing in lines for hours trying to get vaccinated only to be turned away. In Los Angeles County, for example, about 5.5 million people fall into the priority categories for getting vaccinated, but only about 50,000 people were vaccinated in the first week after the county clinic opened, and many were turned away because the vaccine supplies had run short.

Now, public health experts have repeatedly told us that once people are turned away, it is very hard to get them back to be vaccinated. So my question is have the early supply shortages seriously damaged the goal of vaccinating all Americans? And where do you think the point of balance is between your public messaging intended to raise public awareness about the dangers of H1N1, which raises the demand for the vaccine, and the current limited supply of the vaccine?

Dr. FRIEDEN. Thank you.

As you point out, anytime someone comes to a doctor's office or goes to a vaccination site, and there is not vaccine available, the likelihood they will return to that site is less than we wish it would be. That is why we are so frustrated to not have the amount of vaccine available when people want to get vaccinated.

Our goal has always been that the vaccine should be available to anyone who wants to be vaccinated, starting with the priority groups, understanding that many people choose not to be vaccinated, and that is their choice. There is no mandatory vaccination as a part of this. We are currently at 32.3 million doses available for ordering and distribution. It is not nearly where we would like to be.

What we can predict is that the demand for vaccine will be dependent on multiple factors, including how much disease is in a community, how high-profile that disease is, and also an extent to which the vaccine shortages tend to increase demand for vaccine.

We are seeing in this season unprecedented demand for seasonal flu vaccine, even though the seasonal vaccine doesn't protect you against H1N1, and seeing also shortages of seasonal flu vaccination. The seasonal flu vaccine distribution system is done completely differently than H1N1 is done, with 90 percent of seasonal flu vaccine being ordered directly from the distributors by doctors, pharmacies, and others.

But absolutely the fact that there is not H1N1 and seasonal flu vaccine currently in providers' offices when people want to get vaccinated means that some of those people who want to get vaccinated and would benefit from it in all likelihood unfortunately will not get vaccinated in the future.

STATE AND LOCAL PLANNING

Ms. ROYBAL-ALLARD. And after the initial waiver of vaccinations, what will be the strategy to reach the rest of the non-high-priority population? And how are you communicating that message to the public?

Dr. FRIEDEN. Each State operates differently, and we at CDC have provided, with the support of the committee and Congress, about $1,500,000,000 to States and localities for planning and administration of vaccine. Some States are working through managed-care organizations, some through public vaccine clinics, some through private provider offices. Many are doing school-located vaccine clinics, and we have some excellent examples of each of those things working very well. But we have left it up to each State to identify the strengths within their jurisdiction, and then to support them in doing that. And I don't know if my colleague from Alabama would like to say more.

Dr. WILLIAMSON. Yes, ma'am. I think the answer to the target populations, at least in Alabama, we are trying to match the target population with the provider most likely to see the target population. For example, our plan, for example, originally to reach children in kindergarten through 12th grade was to do school-based vaccination clinics. Well, we still hope to do that, but it has been pushed further into the future.

To reach pregnant women, we have obviously reached out to our ob/gyn community and family practice physicians, we have reached out to our federally qualified health centers. And we have done that for all of them.

But then underlying that, we also recognize that there are going to be patients who don't have a primary care provider who are in one of those target populations. That is why last week we held across our State statewide vaccination clinics throughout our county health departments. We will continue to do that.

Our strategy is as long as the vaccine is limited, we are going to push vaccine into the private provider community, target the population. We are going to have an underlying safety net of community health centers and public health departments to serve other people.

I think the concern is once there is enough vaccine, whether that is late December or January, then it is going to be the challenge of reaching out to people who have self-deferred and not come in. And in Alabama one of the things we have said is that while we are trying to reach the target population, anyone who gets in line we will vaccinate, because once we turn them away, we are not sure they will ever come back. That was the experience in 2004 when the last vaccine shortage occurred.

## FILL/FINISH ISSUES

Mr. OBEY. Time has expired. Let me just ask one other question before we break. I understand that the vaccine grows the same—at the same speed, whether it is thimerosal-free or not. But my understanding was that filling and finishing took considerably longer with the thimerosal-free vaccine.

Let me call on the clerk to simply expand on that, because I am still not sure whether or not there is any delay in delivery because of that problem.

Dr. FAUCI. That was the point I was trying to make, Mr. Chairman, is that the—it is easier obviously to have multidose vials, which requires a preservative, than it is to have single small-dose,

thimerosal-free or prefilled syringes. There is no doubt about that. That is a fill/finish issue.

The issue that we are facing is much less a delay in fill/finish than it is of delay in how the virus grows. So that is the reason why I said obviously you may be able to cut some time off in fill/finishing, but the fundamental basic problem is the virus not growing well.

Mr. OBEY. We understand that. I was just trying to figure out how many additional problems we have.

Dr. LURIE. So let me maybe jump in and add to that. When it began to look earlier on in the fall, and maybe even earlier than that—I can't recall exactly the dates—that we were going to have this low growth and fewer doses of vaccine, we worked with the companies pretty quickly to say "do everything you can to maximize the number of doses that get out there quickly regardless of whether that is in a prefilled syringe or a multidose vial." The fastest thing to fill is a multidose vial that has thimerosal. And we asked the companies to differentially first fill as much as you can in your filling lines that use multidose vials. If you have stuff left over, by all means put it in prefilled syringes, but don't hold up the number of doses that we are going to be able to get out quickly because of the need to fill prefilled syringes.

So from that perspective, yes, it had a little impact. I think it had very little impact.

Mr. OBEY. We are going to have to recess to vote. We will be back as soon as we can.

[Recess.]

Mr. OBEY. Ms. McCollum.

Ms. MCCOLLUM. Mr. Chairman, people have talked about the time line and everything else, and I just want to really be clear about the amount of vaccine.

There is misinformation in the media that the reason why the vaccine doses weren't delivered on time is because there has been a huge government takeover of the health care system. And it is in the widely circulated talk radio, and it is part of an experiment on government health care.

Now, the government, the Federal Government, has CDC doing research and investigation, NIH out there working. Everybody is out there doing the best that they can. So if you could just walk through what is a public/private partnership that you keep referring to that you went out and you asked—my understanding is the different organizations of the Federal Government went out and said, how much vaccine can you provide? The private companies gave you an estimate on how much vaccine was going to be available, and there was a shortfall. And are they back on track to get caught up? Because this was not—the Federal Government does not have a vaccine plan where the three of you were overseeing the eggs and making sure the vials were done; this is a private company that does that.

So what have the private companies told you about why they were so off from what they originally promised our government, so that when you made the phone calls to the State, and the State made the phone calls to Mr. Fulton as to how much vaccine we are going to have, what have they done to get this back on track? And

how concerned are you about what we are starting to hear about possible shortages of the regular flu virus?

Dr. LURIE. That is a lot of very good questions, and let me take a stab at this.

I mean, this is a public/private partnership. Much of the vaccine development, therapeutics development and others, are all public/private collaborations of one kind or another. There is a pretty substantial investment in the basic science of doing all this and the clinical science of this. Much of that investment has been through NIH. There is investment to take things that show a lot of promise, make it through early clinical trials, to take things to——

Ms. MCCOLLUM. Madam, my time is limited. I want to know about the shortage.

The manufacturers gave the administration a targeted amount of vaccine that they thought they were going to have available.

Dr. LURIE. And why didn't they.

Ms. MCCOLLUM. It is not available, and it is not—it wasn't anything that any of you or anybody in the Federal Government had any control over, correct?

Dr. LURIE. That is exactly right. That is exactly right. And largely, as I think we had talked about before the break, the biggest problem had to do with this growth of the virus. And the experience historically with growing virus was very different than the experience with growing this particular virus, and that is why we need to get away from making vaccines that depend on us to grow it.

Ms. MCCOLLUM. Thank you.

So when people are out getting misinformation saying the reason why we don't have enough vaccine is because of government takeover, and because the Federal Government blew it, and, you know, you can't trust them with your health care, what kind of effect does that have? That has a trickle-down effect when this kind of misinformation is repeated over and over and over again. And there is a shortage because the manufacturers in the private sector didn't deliver as much as they thought they could originally on time.

Mr. Fulton and your colleague, what kind of effect does that have with all the other messages you are trying to get out to reenforce that, when this misinformation continually is repeated, don't trust the government when they tell you something about the flu?

Mr. FULTON. Well, we usually talk about don't trust the Federal Government.

Local public health is very much in the business of communicating messages to people, and when our messages are inaccurate, that lessens our credibility. And when our credibility is lessened, the messages that we are getting out about, you know, don't smoke, exercise and things like that are tainted by the fact that we have bad information.

We cannot control the media. We have learned that from a long time ago. There are lots of messages that come out. I have had staff come in and say, gee, the other day I heard somebody on the radio say that you don't need to have a fever, and you still have H1N1. Well, that is not the message we are getting out. Our message is this is what H1N1 looks like when you get it.

But there are lots of poor messages out there, and we try to do the best we can. If we have to tell people, yeah, we don't have vaccine, as I mentioned in my remarks, that is going to affect our credibility.

Dr. WILLIAMSON. And I would just echo that I think in this specific circumstance my concern is that our inability to deliver the vaccine on the schedule that it was planned have two effects. One is that undermines credibility, and it leads to people also questioning, well, if they didn't produce the vaccine when they said they would, then is it really safe? And the second thing that I worry about is our ability to deliver this vaccine later in the influenza season when historically people aren't looking for vaccines.

PHARMACEUTICAL COMPANY GOOD FAITH BENCHMARKS

Mr. OBEY. Dr. Fauci, did you want to comment?

Dr. FAUCI. Yes.

Mr. Chairman, your point is very well taken. And I agree with what my colleague said here, but I don't want anyone to get the impression that it is the drug companies' fault that this is happening, because the drug companies, in good faith, contracted with the government to get a certain amount of doses for the flu season. With that comes benchmarks of when you think they will be delivered. The fact that they are not has to do with what we have said over and over again during this discussion, Mr. Chairman, that the virus doesn't grow very well.

But the one thing that I think would be a misrepresentation and unfair is that it is their fault because it didn't grow very well. It is just the nature of the biology of the virus that created an expectation that we thought there would be a certain amount. That expectation was shared with the American public, and there is a disappointment that is frustrating and all. But I would hate to see it said that, you know, we did everything right; it is the drug companies' fault, because it really isn't.

Mr. OBEY. Mr. Bonner.

IV INJECTION

Mr. BONNER. Thank you, Mr. Chairman.

I was initially going to ask this question of Dr. Frieden, but I think I am going to focus it to Dr. Lurie because she actually mentioned it in her opening statement, and it really deals with the issue of an IV injection.

As the committee knows, the vast majority of H1N1 inoculations will be administered by either the spray or by needle, but for a small minority of patients—I think you referenced this, I know it is in your written testimony—would need to receive the antiviral inoculation intravenously.

And my question to you is we have a pharmaceutical company in Alabama, full disclosure, not in my district, but in my home State, that produces the drug Peramivir that I believe you mention in your written statement, which is designed to be administered through the IV. As I understand it, the FDA has not yet approved this drug, but last Friday HHS issued an emergency use authorization to allow CDC to distribute this to eligible entities.

So my question to you is can you speak specifically about the emergency use authorization for this drug and whether the courses are going down according to the schedule? And would you anticipate CDC having enough courses to handle the potential surge of patients into ICUs?

Dr. LURIE. First, let me just clarify something so that there is no confusion here. The vaccination that is either injected or through nasal spray that we have been talking about all morning is what you give to prevent people from getting sick. The antiviral is what you give to people once they are sick to prevent further complications.

Most antivirals are oral. There has never been an IV form of an antiviral before. And with the investment that has been made, three companies are now working hard, or at least three companies are now working hard on making IV antivirals, and one of them is Peramivir.

Peramivir has shown a lot of promise. It has been available as an investigational new drug, sort of on compassionate use, but hasn't had really, really large-scale use in people yet. And so there is not enough accumulated experience and data for it to qualify for full licensure yet by the FDA. The company is still putting that material together, doing clinical trials, getting that experience. However, there was clear judgment made that there was enough experience with it clinically and with its safety profile that, given the severity of disease people were getting, it could be available under emergency use.

We have bought an initial number of doses, we are watching very carefully the burn rate of those number of doses, and we intend to continue to buy IV antivirals so that we don't run out and so that we have a supply of antivirals that is well ahead of what we are seeing now in clinical illness.

That said, if the disease took a really terrible turn for the worse, you know, we would be pulling all the stops to manufacture all the IV antivirals we can. But that is where we are.

Mr. BONNER. And, Dr. Williamson, along that line, how helpful would it be to you, as a public health official for a State, to have antivirals, IV antivirals, available, prepositioned, as opposed to being—where I understand they currently are in a single location in Maryland?

Dr. WILLIAMSON. Congressman, I think I can only answer that based on our experience with the existing stockpile. The existing stockpile, having the stockpile available admittedly—that is an FDA-licensed product. Having the stockpile available allowed us to push out 100,000 doses.

I think if there is a benefit, that benefit would be if it shortens the time from demand to the patient, and that, to me, would be if there is a benefit of it being prepositioned in the States, it would be if that in some way gets the drug more quickly to the patient. I think there are issues obviously about who is eligible and those sorts of things that would have to be worked through. But that would be the only advantage I see.

Dr. LURIE. There is a pretty good system, I think, that's now in place so if a clinician recognizes that a patient is doing badly and that they might need a drug, they can actually order this through

a Web site. There are people at the other end also to answer questions. That information is very rapidly transmitted electronically to the warehouse, and those doses are shipped.

H1N1 VACCINE DISTRIBUTION

Mr. BONNER. And just so I can get a grasp, by very quickly or very rapidly processed, what would be the time line on something? If a doctor in a hospital sees a patient who, this or any—I am using this as an example, but really it goes to kind of the questions earlier in terms of understanding the time line and the process. What would be a quick response?

Dr. LURIE. CDC is managing it, so I will let Dr. Frieden respond.

Dr. FRIEDEN. We have a 24/7 response to this, and commit to have the drug delivered within 24 hours. It is maintained at the manufacturer's site, vendor managed, inventoried, shipped directly to the point of use. And as Dr. Lurie mentioned, there is a Web site for on-line ordering as well, so it can be done very quickly.

Mr. OBEY. Ms. DeLauro.

STATE VACCINE ALLOCATION

Ms. DELAURO. Thank you very much, Mr. Chairman. And I apologize for coming in and out, but I want to thank you so much for calling the briefing, and all of you are here today to help enlighten us through this briefing.

I am going to try to get through three questions fast, given the time allotment. The Post yesterday, the Washington Post, had an illustrative article regarding what is happening at the ground level in doctors' offices and with pediatricians. The article pointed out that the system for distributing it to private doctors' offices is opaque, and that it is not clear to the public or the doctors who is going to get what when.

So what is the delivery system for doctors' offices? Who decides who gets what, and what amounts?

Dr. FRIEDEN. Each State receives, or each jurisdiction—there are 63 jurisdictions—receives an allocation that is strictly based on population. That jurisdiction, States or some cities and territories, then decide how they will allocate that to schools, public clinics, hospitals, private doctors' offices based on their best judgment of how they will get as many people vaccinated as promptly as possible.

Ms. DELAURO. So then it becomes the State's decision to deal with this and how it is done.

Okay. I will get to the seasonal flu issue in a second, but let me ask this question, because we have those hearings, avian flu, seasonal flu, now H1N1. I am talking about infrastructure, you know. We talk about roads, we talk about bridges, we talk about modernizing our schools, we talk about broadband, all of these efforts of how we try to take this infrastructure and build, you know, for the future here.

What is the infrastructure, Federal, State, local level, that includes—and where industry fits here—that will not have us have this same hearing over and over and over again? It is a little bit like Groundhog Day, because we are always—there is some sort of a shortfall. We don't have enough of this. What is the infrastruc-

ture? What would it cost? How do we adequately prepare and have an infrastructure in place to manufacture and to distribute vaccine whenever something comes up here for us to have to deal with it so that we have got a structure in place to move forward?

From my perspective at the moment, it seems to be that it is bifurcated, it is—we are relying on people overseas. The delivery mechanisms seem to be faulty in some way. How do we get this to be an operational system that saves you the problem of having to answer these questions over and over again, and us having to ask the questions over and over and over again?

Dr. FRIEDEN. Thank you very much. I think if we start with the delivery system and work backwards, we first need to ensure that at the local and State level we have the infrastructure. You heard earlier this morning about the enormous challenges that exist there. We at CDC provide some guidance, training, and staffing to support the work of State and local health departments, but nowhere near what is needed. That infrastructure is needed to deliver any tool that we have available.

VACCINE TECHNOLOGY

Ms. DELAURO. Do you all have a plan as to what it would be, how it would be, and what are the resources? I would guarantee, and I do not know if I am speaking just for myself, but I think I speak for—when it comes to this kind of an issue, this committee is willing to put resources at disposal here in order to get to where we need to go when it regards the public health. If you do not have it, I would welcome your having this kind of information to get.

Dr. FRIEDEN. There are a variety of estimates of what it would take to strengthen the State and local capacity in terms of tracking capacity, laboratory capacity, and the workforce need. Those would be the three key areas at the State and local level. At the Federal level, there is also a need to track diseases better both in the U.S. and globally. This disease emerged globally, and much of our information on how it is going is dependent on what we can track globally. So there is a need for State, local, Federal and global, public health infrastructure in order to track and respond and deliver vaccines, deliver antivirals, monitor the course of the epidemic.

More upstream there is a need, as Dr. Fauci and Dr. Lurie outlined, of investments in new technologies so that we can get out of the egg era and into an era when we can respond within weeks or months to a vaccine becoming available.

Ms. DELAURO. Protein?

Dr. FRIEDEN. There are a variety of promising potential technologies.

Dr. LURIE. We seem to only invest after there has been a crisis.

Ms. DELAURO. And I am asking you——

Dr. LURIE. We have to get ahead of this crisis.

Ms. DELAURO [continuing]. Really, to provide us with what is the investment plan and what is involved, who is involved. You know, then it becomes—you will look to us, and then we have a responsibility to deal with it.

Dr. LURIE. We will have to get back to you with that.

Ms. DELAURO. Thank you. Thank you.

Mr. OBEY. Mr. Lewis.

H5N1 AVIAN INFLUENZA VIRUS

Mr. LEWIS. Thank you very much, Mr. Chairman. This kind of discussion is not just overdue, but very welcome. During the brief time I had a chance to chair the committee, I got to know some of the people who had the privilege of working in this arena with Dr. Fauci. I will not forget that first discussion with Julie Gerberding, in which we were talking about avian flu and the prospect of its metastasizing and the impact potentially on humans. I thought you said earlier, Dr. Fauci, that perhaps avian flu responded a different way to vaccines that were available. That would imply metastasizing.

Dr. FAUCI. No, no, let me clarify. As you know, the H5N1 avian influenza had the capability of being very virulent, but was very, very poor in spreading from person to person, if at all. There were only less than 500 cases and about 270 deaths. So it is still smoldering. But in our preparation, our pandemic influenza preparedness plan, Ms. DeLauro, that you are talking about, was to do the kind of things that actually were in place which really did help us to respond as best as we could to this one.

We are not really where we want to be, but in specific answer to your question, Mr. Lewis, we made a vaccine against the H5N1, and the issue was that it was not particularly good in inducing a response in humans. So the dose that was required for that particular vaccine was outlandish. It was 90 micrograms times two, which would induce a response in only 50 percent of the individuals.

When I was making my presentation, I was saying that fortunately, the H1N1 vaccine that we tested at the NIH, a standard 15 microgram dose induces a very robust immune response with one dose in virtually everybody except younger children.

So the frustration is that we do not have the vaccine available right now for everyone who wants it. The good news is that when we get it into people, it is predictive of being highly protective.

VACCINE PRIORITY GROUPS

Mr. LEWIS. Very much along those lines, there are three groups of people that concern me at this moment. They very recently made an effort to have a daughter in our family who is pregnant get the vaccine. And it was not available in this environment, and so they found themselves standing in line over the weekend for some considerable length of time.

That is problematical in and of itself, just the waiting in line. But a second group worries me a lot. That is two grandchildren who were in a family where the mother suffers from asthma. Who should be vaccinated first, the children or the mother?

Dr. FRIEDEN. You have identified three key groups to get vaccinated. And from CDC we have said basically that all of these groups should get vaccinated, even though there is not enough vaccine for everyone who would want it. Now, we do not want people turned away and told to come back, because they may not come back in the future.

There are different reasons to prioritize each of them. Pregnant women because they are at higher risk of hospitalization and

death, people with asthma because they are at higher risk of severe hospitalization, and kids, because they have a higher rate of getting the disease and risk of getting severely ill.

Mr. LEWIS. What about kids under the age of 9 who also happen to have asthma?

Dr. FRIEDEN. Also a high risk group, absolutely.

Mr. LEWIS. Well, the person I was asking that for is not here presently. They are planning to have the first shot shortly. But you were suggesting they really need to have the second shot?

Dr. FRIEDEN. For 9-year-olds and under it is required to have 2 shots to get a robust response, as Dr. Fauci's studies show.

DDT USE IN AFRICA

Mr. LEWIS. Okay. If I could, Mr. Chairman, just one more item. When I was talking with Dr. Gerberding some time ago, we were—part of our discussion beyond avian flu was to discuss AIDS in Africa. And she said that it is good that we had an interest in impacting that, but indeed malaria in Africa was perhaps a greater challenge. And for the first time, Mr. Chairman, I heard about DDT and the impact it had on malaria here and otherwise. And we banned it from this country. But she essentially said that DDT has the capacity for staying lifetime in the huts of villages in Africa. That struck me as being amazing. It is a lot better than depending upon netting. But is that a reality? Are they using DDT in Africa?

Dr. FAUCI. Yes, there is a plan now of doing multiple things. One is insecticide-impregnated bed nets. The other is spraying indoors along the rim of the huts, not globally out in the environment, but indoors in the huts. The other is prophylactic treatment for pregnant women. And the other is artemisin in combination therapy for malaria. Those are the four components of what originated as the President's Malaria Initiative, which is being continued in this administration.

Dr. FRIEDEN. And those components are highly effective. CDC has staff in country and all of those places working with health ministries. Places which have implemented those four components well have been able to cut malaria by 50 percent to 80 percent.

Mr. LEWIS. I have asked a follow-up of my sources in California, but it might be better to ask you and see if you can help us, DDT was banned because of the impact it had upon humans, especially when used on food sources. But if we are allowing DDT to be used in Africa, have we got a program to try to try to follow up and see what impact it has upon, you know, the health and existence or life span of these people?

Dr. FRIEDEN. A variety of different insecticides are used in the program. Some countries do allow use of DDT, but only under very strict procedures. If it gets mixed in with the crops, that can have an economic dislocation effect for the countries, and it has to only be used in an indoor area. The risk of DDT is the risk of going into the food system. But absolutely it needs to be done very carefully.

Mr. LEWIS. The risk within the hut, if indeed it is used there—can have a long term—do we know if it has a long term impact upon the health of those children that live there? Which is really the kind of thrust that I would like to begin to pose.

Mr. Chairman, as you demonstrated so well, these issues absolutely have nothing to do with politics and it is really a helpful exchange. I appreciate it.

Mr. OBEY. Thank you. Mr. Jackson.

Mr. JACKSON. Mr. Chairman, if you do not mind, I would like to come after Mr. Honda, if that is quite all right.

Mr. OBEY. Mr. Honda.

CELL-BASED TECHNOLOGY AND MOLECULAR TECHNIQUES

Mr. HONDA. Thank you, Mr. Chairman. And thank the panelists for being here. A couple of quick questions.

The first one just requires a written response from CDC and HHS. And that is the distribution of the vaccine that has already been out there. Santa Clara County was supposed to get about 100,000 vaccines. That would have been 45 percent of what has been distributed. Or say 45 percent of the amount of vaccine we were supposed to get in Santa Clara County is down to about 23,000. So it is cut almost 20,000 that is unaccounted for at the State level. We can't seem to get an answer as to where they are or what the distribution format was.

Can CDC or HHS find out for us or do you have oversight on the distribution to the local level through the State? And that is the first question I would like you to respond in writing, if you would not mind.

H1N1 VACCINES

Mr. HONDA. Santa Clara County was supposed to get about 100,000 vaccines. That would have been 45 percent of what's been distributed, and so 45 percent of the—the amount of vaccines we were supposed to get in Santa Clara County is down to about 23,000 now, so there's—you know, there's about 20,000 that's unaccounted for at the state level, and we can't seem to get answers to where they are or what the distribution format was. Can CDC or HHS find out for us? Or do they—do you have oversight on the distribution to the local level to the states?

Dr. FRIEDEN. CDC does not have information or oversight for where and how many doses have been shipped to a specific local health department/private provider, as that is up to the state's discretion and authority (with the exception of Los Angeles County, as they are a separately funded grantee). For information about local distribution in California, please contact John Talarico at *John.Talarico@cdph.ca.gov*.

The other question I had was I also heard, and get a response in writing also, is it true what I heard that there is mercury being used in the vaccines that we are receiving that is being produced? And if so, why? In light of the effect that mercury has on young children.

THIMEROSAL IN VACCINE

Mr. HONDA. The other question I had was I also heard—you know, if I could get a response in writing also—is that is it true that what I heard that there's mercury being used in the vaccines that we are receiving that's being produced? And if so, why, in—in light of the effect that mercury has on young children?

Dr. LURIE. Thimerosal, a mercury-containing compound, is a preservative added in small amounts to multi-dose vials of some vaccines to prevent the growth of bacteria or fungi that may be inadvertently introduced into the vaccine during use. Contamination by germs in a vaccine could cause serious illness or death. Preservatives are not required for products formulated in single dose vials. The recently licensed inactivated ("flu-shot") H1N1 vaccines are available in both thimerosal preservative-free single dose formulations and thimerosal preservative-containing multidose formulations. The live attenuated seasonal influenza vaccine (FluMist)

and the corresponding H1N1 live attenuated vaccine contain no thimerosal. Thimerosal has a long record of safe and effective use preventing bacterial and fungal contamination of vaccines.

In 1999, in response to the FDA Modernization Act (FDAMA) of 1997, FDA conducted a comprehensive review of the use of thimerosal in childhood vaccines and found no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity (allergic) reactions (Ball et al. 2001). Furthermore, a number of studies were conducted to address public concerns about a potential association of thimerosal in vaccines and neurodevelopmental disorders, including autism. These studies were independently conducted by different investigators using various designs in different samples and countries, (e.g., Sweden, Denmark, United States, United Kingdom and Canada), and all have consistently provided evidence of *no* association between thimerosal-containing vaccines and autism, despite the fact that different methods were used and different populations were examined. In 2004, the IOM's Immunization Safety Review committee concluded that this body of evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism. Since then, additional studies conducted in 2006, 2007 and 2008 provide further support that thimerosal exposure of children from vaccines is not associated with neurodevelopmental disorders. Three leading federal agencies (CDC, FDA, and NIH) have reviewed the published research on thimerosal and found it to be a safe product to use in vaccines. Three independent organizations [the National Academy of Sciences' Institute of Medicine, Advisory Committee on Immunization Practices (ACIP), and the American Academy of Pediatrics (AAP)] reviewed the published research and also found thimerosal to be a safe product to use in vaccines. Thus, the available evidence supports the scientific conclusion that currently licensed vaccines containing thimerosal preservative, including some formulations of H1N1 vaccine, are safe.

The one I would like to hear from you right now is the Congress has allocated about $6.8 billion over the last few years for pandemic preparedness. And hearing your testimony today, there seems to be a lot of barriers and glitches along the way. I understand the fill and finish issue, where there is a lot of time delay there. I guess I want to get away from using the egg to the cell-based. And I think someone mentioned, maybe you, Dr. Fauci, you mentioned about using molecular level science and site-based—I forgot the rest of the phrase that you used.

Could you expand a little bit more on that and why you think that that might be more efficient and what we are faced against when we look at production of eggs and using the egg approach, which is archaic by some of your words versus the current technology that we have in front of us?

Dr. FAUCI. That is an excellent question. I would be happy to answer it as succinctly as I can.

We right now overwhelmingly have an egg-based technology, which has the vicissitudes that we mentioned. One of them is the growth, you can get contamination, et cetera. The plan is to move to a much more reliable cell-based technology, which still requires the growth of the virus, and does not eliminate all the fragility of the system. The end game for us is the investment which we are making and the ability to scale up in the arena of molecular techniques.

Let me give you one example of a molecular technique that is probably the more advanced of a group of about five or six that are being pursued, everything from the fundamental basic research at the NIH up through and including the partnership with the companies to get it, and that is instead of relying on the whole virus to grow, the part of the virus that is the immunogenic part that you want the body to make an immune response against is a thing called hemagglutinin NRH. You can take the gene of that and you

can insert it in a virus that happens to infect insects. It is called a baculovirus, which you grow in insect cells. You can have a great deal of control of the amount you do, the growth you do. So what comes out is not the whole virus, but just the purified protein that you want.

The NIH was involved in the phase two trials with the company. The company has now done phase three trials for efficacy, and are in the process of applying to the FDA for licensure. That is the good news. The challenge ahead is how do you get that technology to be scaled up enough to essentially replace completely the fragile technology.

So what we are going to be seeing, Mr. Honda, over the next few years, and it is going to take years, because that is the nature of the process, as fast as you go, is a gradual transition from egg-based to egg-based together with cell-based, to cell-based to advanced molecular technology.

The ultimate end game for all of us, and where we are aiming our research at the NIH, is to get what is called a universal vaccine. A universal influenza vaccine is a vaccine that would induce a response to a component of influenza that does not change from season to season and that does not change whether you have a pandemic strain or a seasonal strain. And that, if you can do it, that would be the end game.

You mentioned that, Ms. DeLauro, the end game, because then you could make as much as you want and you could store it, you do not have to change from season to season, and you could inject people, get them immunized, and immune and protected, and then perhaps every few years thereafter do it again. That is the plan. That is going to take years.

VIRUS MUTABILITY

Mr. HONDA. It seems like with that approach the mutability of the virus can be approached much quicker. You have a baseline from which to work.

Dr. FAUCI. You could even bypass it. Because influenza A, which is the one that is usually the culprit, is influenza A. It could be a pandemic, it could be a seasonal, it could be an H3N2, an H1N1, it is still influenza A. There are parts of that virus that the body does not seem to make an immune response that stays constant even as the virus changes.

What we are doing now is identifying those parts we call cryptic components to put in a form that when you vaccinate somebody they will make a response that will protect you against any influenza. That is where we are aiming. But that is not going to be easy, but it is doable.

Mr. HONDA. This feels like something where a company is trying to protect their patent, and just changing the site of each item gives it an opportunity to create another patent. It is not like that or something.

Dr. FAUCI. No, it is not.

Mr. OBEY. The gentleman's time has expired.

Dr. FAUCI. That may be a problem, but that is not this problem.

Mr. OBEY. The gentleman's time has expired. Mr. Cole.

Mr. COLE. Thank you very much, Mr. Chairman. I apologize for missing some of your presentation. I had other engagements. So I beg your pardon. I may cover some ground that you already covered, so forgive me if I do.

As I went the through the material and listened to some of the testimony, one of the things that struck me, perhaps not accurately, and Dr. Lurie or anybody can take the question, was how much of the product that we need is dependent upon foreign manufacturing? So one, is that a correct problem? Two, what are the reasons why so much production is elsewhere as opposed to here, if that is indeed a challenge?

Dr. LURIE. Sure. Right now there is one manufacturer that manufactures entirely within the United States, a second manufacturer that does partially. And there are—everybody is more able to fill and finish the vaccine but not make the antigen within the United States. That is an historic problem that had to do with investment in the vaccine infrastructure, the profitability of making flu vaccine. Flu vaccine historically has not been very profitable. When this problem was recognized several years ago, a couple things happened. We took very aggressive actions to get manufacturers licensed even to sell vaccine in the United States, and then aggressive actions to rebuild the manufacturing infrastructure within the United States precisely because we do not want to be dependent on a situation where everything we need to protect the public is manufactured elsewhere.

Mr. COLE. Are there specific things that Congress should be doing to sort of assist you in making sure that we do not have that kind of challenge going forward?

Dr. LURIE. Well, we need to continue to invest in manufacturing capacity in the United States. We have started to do that with the cell-based facility that is going to open or begin startup next year and is having an opening this fall. But that will only get us for cell-based maybe only half of where we project we need to go to be prepared.

So we need to continue to invest in that large scale manufacturing capacity in the United States, but with our eye on the end game so that when we have the new science we are then not another 5 years behind with scaling up that manufacturing capacity.

So that is going to be a continuous process for a while, and it is going to take some substantial investment.

Mr. COLE. Let me ask the second question. Obviously, all this I know you more than anybody else are somewhat disappointed that we put out information that we were not able to fulfill in terms of commitments. When along the process did you begin to have the sense that we were going to come short? And what, if anything, differently should we have done in terms of trying to lower the expectations? I think that is one of the challenges that you have today, that you all have.

Dr. LURIE. Well, I think it is fair to say that there are a variety of points along the way where we got information that our amount of vaccine was going to be lower than we initially anticipated. At every step of the way we looked at that information, communicated

it as quickly as possible to our State and local partners and to the American public.

So we tried to be, and I think we have been, really transparent about the communication. And there have been multiple points along the way where different things went wrong. You know, whether it was about virus growth, or whether it was about problems with filling lines or other sorts of things.

So each step along the way we have tried really hard to communicate that to the American public. And you walk a really fine line, I will say, between needing to be really transparent and satisfying everybody's needs for projections and ending up with a set of projections where you really fall short. And that has been the challenge.

Mr. COLE. Believe me, I am not trying to be critical. The complexity here just from the hearing here is evident. I just wanted to see if there was something we should have done differently, with the expectations being a real one. We all live with it, and I think it has caused a problem.

Let me ask one last question. I am sure just like the military, after you go through an exercise like you are still in the midst of, you do a lessons learned and what would we do different. One, what is the timeline for that? And two, is that something that appropriately could be shared with this committee? Because I think we would all like to see what the process is as you go back and reevaluate.

Dr. LURIE. I expect that at all levels we will be doing a lot of that. We have already begun doing some of that within my office. And I think really across Federal, State, and local levels we need to do that because we need to be better prepared for the next time. And we are always asking ourselves what could we do better? What could we do faster? What did we learn from? And in fact, you know, our ability to respond to this is really because of lessons learned from other kinds of events. So that is already underway.

Mr. COLE. So will that be in a document that is publicly available so folks can have a look at?

Dr. LURIE. I think we intend to be fully transparent with all of this.

Mr. COLE. Thank you very much. Thank you, Mr. Chairman.

### DELAY IN VACCINE AVAILABILITY

Mr. OBEY. Let me make a few observations and ask a few questions. First of all, I have forgotten whose testimony it was that indicated that we lost about 15,000 public health personnel in States around the country. I would like to simply point out that that occurred despite the fact that we put billions of dollars in the stimulus package into efforts to stabilize State budgets. And as a result, that package this year has filled about 40 percent of the States' budget holes. The problem is that next year the remaining funds in that stimulus package will only fill about 20 percent of State budget holes so we are going to have a problem at the State level in terms of budgets twice as bad as the one we had this year. And if we do not do something about that, we are going to lose a whole lot more people, not just public health personnel. One observation.

Let me ask a question. Will the delay in this vaccine result in a delay in the regular seasonal vaccine's availability?

Dr. FRIEDEN. No, we do not think so, although the other way around is the case. There were delays in growing this year's seasonal flu vaccine which delayed somewhat the start of production of this vaccine.

Mr. OBEY. All right. You have all been very reluctant to make any further predictions about how many doses you are going to have and when. Let me ask what might appear to be a cynical question: are we going to have an appreciable amount of this vaccine delivered after the second round of the flu hitting people is over?

Dr. FRIEDEN. I think there is no question that currently we are continuing to see virus activity, the number of people getting sick increased in many States, although it has already begun to decrease in other States, particularly in the Southeast. So it is likely that the current wave of infections will peak, crest, and begin to decline before there are ample supplies. Whether there will be another wave of H1N1 between now and May, when flu season ends, or whether we will get a different strain of influenza, only time will tell.

Mr. OBEY. It appears that we have relied upon the estimates of manufacturers in order to determine what our expectations were in terms of the availability of vaccines.

Have you been able to develop in any way a process which would enable you to make judgments that are independent of the estimates of the manufacturers with regard to that question?

Dr. FRIEDEN. We really are dependent on the production facilities to tell us what they can produce. Dr. Lurie may want to describe that more.

Dr. LURIE. No, I would agree with that. And we are very dependent, as you have heard, about what those yields are to do anything. And in fact even with making projections early, making assumptions the yield would be lower even than they told us, we still got into this bind. Once that stuff is made, as I said, we are tracking lot by lot every step of the process. So from there on we are developing more comfort, but not complete comfort.

VACCINE PRODUCTION

Mr. OBEY. Are you satisfied that the manufacturers notified you immediately after they got their first inkling that things were going to be developing more slowly than they expected?

Dr. LURIE. You know, we have had communication with the manufacturers every week, and I would say there has been a really good exchange of information throughout this process.

Mr. OBEY. So the answer would be——

Dr. LURIE. I mean obviously nobody knows what they do not know, but I think that this has been a really good collaboration and that there has been a very good exchange of information.

N95 RESPIRATOR PRODUCTION AND USE

Mr. OBEY. Okay. Let me ask about respirators. According to HHS documents, as of June 2009, 102 million N95 respirators were purchased for the Federal stockpile. The Bureau of Labor Statistics es-

timates that there are just under 14 million U.S. workers employed in the health care industry. Of those 102 million respirators apparently provide only seven N95s per health care worker. Considering that OSHA estimates that an average of four N5s are used per 8-hour shift, would not this number seem shockingly low? What is the rationale for stockpiling that low number of N95s? Why not more?

Dr. FRIEDEN. The global production capacity for N95s cannot keep up with the demand that would be used to comply with the CDC recommendations for use of N95s for health care workers caring for people who might have H1N1 influenza. The stockpile is meant to address not just influenza, but a whole range of infectious disease conditions that might benefit from respirator protection through N95s.

Mr. OBEY. If the global capacity is inadequate, what can we do about that?

Dr. FRIEDEN. In the guidelines that CDC issued, we outlined a series of steps which health care facilities can take to preserve and limit the use of N95s so that the highest risk procedures and the highest risk situations we have N95s——

Mr. OBEY. What can we do to boost the capacity for production?

Dr. FRIEDEN. It is only recently that CDC has recommended use of N95s for health care workers caring for patients who may have H1N1 influenza. This has big implications for supply and for the market. And I think as we get through this flu season we need to look at what the stockpile should or should not have.

## VACCINE SCIENCE AND DELIVERY

Mr. OBEY. Look, just one last point, I am not especially known around here for being patient, and yet I have been hearing this stuff for five years. I just want to quote a couple statements from hearing transcripts in 2004 and 2005.

In October of 2004, Dr. Gerberding in her opening statement said, "we need to prepare for pandemic influenza; a time bomb is ticking."

I then asked her a number of questions. I asked, "Is there something the government can do to help regularize the annual vaccine supply that we have? For instance, should or could the government simply guarantee a specific level of market to manufacturers in order to make certain that there is enough incentive for producers to produce it year after year?"

And I went on to say, "it seems to me that if this is a crisis, I do not understand why we cannot bring the lead countries of the world together, the governments and industry people, find out what it would take to develop. If it is physical facilities that are necessary, fine. I understand you cannot do it instantly. But there must be some way to compress the timeframe if we regard this as an emergency rather than merely an interesting problem."

In response, Dr. Gerberding said, "I have to be frank here. Our capacity to develop and produce vaccines for any infectious disease is extremely fragile in this country. We do not have excess production capacity for any one of the vaccines, let alone influenza. The entire global production of flu vaccine is 290 million doses a year. So we are in a very, very fragile situation in terms of vaccine sup-

ply. I think we need to work with the committee to identify ways that we can motivate and expand our overall vaccine production capability. This is a catastrophe waiting to happen. We are at a crisis point here."

In April of 2005, I said the following: "This ought to be a high priority. My problem is I do not really think our government is treating it as a high priority." And I said, "I would simply say that the numbers that are being cited demonstrate our existing program is totally inadequate and not doing the job."

Dr. Gerberding responded, "So I think this is a real opportunity for us to collaborate and really identify, you know, in five years where do we want to be and how are we going to get there and how fast can we get there?"

Now, that was five years ago. And so I mean I heard you, Doctor, say earlier that we needed to do more to increase our investments in producing modern vaccine technology and we needed to do more to regularize demand.

We have been hearing that for five years. I know you are new on the watch, but what does it take by way of resources that this committee could provide over the next four years so that we are not flap-jawing and yapping at each other using the same talking points that we have heard for five years? What do we do? How much do we need?

If there is something we can do, ask us for it. Tell us what we need. I mean we are spending lots of money on lots of other stuff in this budget that is much less important than this. This flu may wind up being not merely as severe as we feared, but by God sometime in our lifetime that ain't going to be the story.

So what do we finally have to do so that we do not chew the same cud year after year after year?

Dr. FRIEDEN. Thank you, Mr. Chairman, for your question. I think that is the essential question that all of us have to address. And it starts with vaccine science, the basic science that Dr. Fauci and NIH does, the applied science that BARDA and Dr. Lurie's unit does, and the delivery systems that CDC and State and local health departments provide. And all of those are, as you said I believe in your opening statement, are pipelines that are rusty. And we need to strengthen them and we need to recognize also that some of the basic science is a question of what is possible. It may or may not work out, but with more investment it is more likely to work out.

Mr. OBEY. Let me say I understand that. I mean nothing has bugged me more in the over 30 years I have been on this subcommittee than to listen to people say, well, if we can send a man to the moon we ought to be able to cure cancer. Well, one was a rather simple engineering problem in comparison to dealing with the multiple kinds of cancers that are out there. So it is a whole lot more complicated.

But having said that, if we were to make this a top priority, what would we do? What would our budgets look like? What is a reasonable scientific expectation if we do A, B, and C, and what are A, B, and C? That is what we are asking.

Dr. FRIEDEN. I can address the delivery system reasonably well. But with additional resources for epidemiology, lab capacity, vac-

cine delivery at Federal, state, and local levels, we can ensure that we can get vaccine out.

FIVE-YEAR STRATEGIC PLAN

Mr. OBEY. Does our government have a five-year plan to try to accomplish that? I do not want to sound like the Soviet Union with its five-year plans, but have we ever or will we ever have a multiple-year plan to try to get there? And if so, what would it look like?

Dr. LURIE. So we had a pandemic plan. Our office is in year three of a five-year strategic plan. I think to Mr. Lewis's point, one of the lessons learned here is pretty quickly to take a look at that plan, where we are in our five-year strategic plan, where the science is, and come back quickly to put together a new five-year strategic plan and work closely with you to see if we can make progress in implementing it.

Dr. FAUCI. Same thing, Mr. Chairman. You know we have been working with each other on this for a long time. And I was there when you were reading all of that testimony. But from the NIH standpoint, as you well said when you were saying it somewhat facetiously, with science it is very, very difficult to predict, because science is discovery, it is not engineering. But we do have a plan——

NIH APPROPRIATION

Mr. OBEY. No, I was saying the trip to the moon was engineering.

Dr. FAUCI. Yes, and I mean, right, science is discovery and the trip to the Moon is engineering. And discovery requires the kind of basic science input that we have and that you generously supported. In 2003 our budget for influenza was $50 million. It is now $260 million at a time when the NIH budget was flat. So we have reprioritized for this emergency. Even though all science feeds upon each other, we have made a significant investment in that despite, as you well know better than anybody in the world, the flatness of the NIH budget.

Mr. OBEY. You wanted to respond?

Dr. WILLIAMSON. Yeah. Mr. Chairman, I think speaking with my local colleagues from the rusty end of the spigot where we are trying to deliver the vaccine, one of the challenges we face, and we need to be very clear, were it not for the funding that you have provided to the States and through the States to the locals for emergency response, and recently through the public health emergency response dollars, we would not be here having this conversation because there would in many States be almost no infrastructure with which to respond.

So the first thing I would ask, and I do not know the number, but the first thing we need to do is to accept that there is some minimum level of infrastructure support that is going to be necessary at the Federal level all the time because State budgets have these fluctuations.

And the other message that I think goes with that is whether or not the epidemiologist is tracking influenza today, they certainly

may be tracking a food-borne outbreak tomorrow. So there certainly is that cross-utilization.

I can speak from Alabama's perspective here, we need almost a Hill-Burton or interstate highway project across the country to replace some of our public health laboratory infrastructure. Now some of the States, like Virginia, have done wonderful jobs in building new labs. But many of us, my State, for example, we are dealing with a lab that was built in the 1970s. And that is fine. They do great work there. But it was designed at a time when public health was not changing, the work they were doing was fairly constant, and it was designed to meet that timeline. It is a $40 million investment for the State. We cannot do that.

So we need that sort of bricks and mortar capacity construction going forward.

Mr. FULTON. I would like to speak to both your question and Ms. DeLauro's point about the shortfalls. The health care reform bill in its wellness package, at a billion dollars a year for infrastructure in local public health and in State public health, will be critical to our continuing to have the capacity to be on the ground when these types events occur.

I do not want money just to hire people to sit around and wait for a flu event. I need the people to be health educators and visiting nurses and clinic staff. And that piece in the health care reform bill is critical, and hopefully it is not one of the things that gets tossed out at the end, much like happened with the stimulus money in the negotiations in the first stimulus bill.

Mr. JACKSON. Mr. Chairman? One quick question. I hope this is not too far off the direction of H1N1. But it occurs to me that while these are dedicated health professionals dealing with a profound problem in the system, and there are problems that we are discovering in the system, I am wondering if this is the same infrastructure that we would rely upon if this were a man-made biological event? Would we be calling essentially these professionals to tell us that the preparations are inadequate?

Mr. FULTON. Yes. The preparedness is the same. It is the same.

Mr. JACKSON. So if this were a man-made biological event, we would be going through the exact same contracting that you are looking for to determine private sector influenza or vaccine-producing entities to distribute to the American people, that we would have trucks lined up alongside these entities trying to distribute them to distribution centers throughout the country.

And it just appears to me that the inadequacy of a—I do not want to say that our response is inadequate because I think that in your testimony, each of you have shown us that we are doing the best we can given the lateness of the mutating nature of this particular event. But, my concern is if this were a man-made biological event, either through a terrorist event or something created in the laboratory that we wish we did not discover, would we be relying upon the same infrastructure to address the distribution?

Mr. Chairman, thank you.

DISTRIBUTION INFRASTRUCTURE

Mr. FULTON. Well, at the local level, yes. We are trained on a variety of different responses. It could be a hurricane, it could be a

tornado, which happens in our neck of the woods, it could be an outbreak of tuberculosis, it could be an anthrax attack. We have practiced and have been trained in a wide variety of those types of events. And it would be the same workforce that is now deployed for H1N1 that would be deployed to provide the services for things like another terrorist event.

Dr. WILLIAMSON. And that is certainly true at the State level. For example, in our case we are using a platform to monitor bed availability in influenza-like illness that we actually designed to monitor bed availability during hurricanes, and used it during Katrina to route patients from our southern part of the State further north so that patients coming from Mississippi and Louisiana would be able to be hospitalized more closely.

So in that sense, absolutely, it is the same epidemiologists who are going to be tracking, whether it is anthrax or whether it is H1N1, it is the same laboratory doing different tests perhaps, but it is the same laboratory and same laboratory capacity or lack thereof that we are dependent on.

Dr. LURIE. Yes. Go ahead.

Dr. FAUCI. Mr. Jackson, you remember we had this conversation at one of our appropriations hearings, and in fact they are exactly the same technologies that we are trying to develop. And I can only speak from the research standpoint, not from in the trenches in the community. But from the research standpoint, we make indistinguishable a man-made biological event and a naturally occurring one. And in fact, in all of our biodefense plans we actually merged those two and call it such and such for biodefense and emerging infectious diseases.

Nature, in my mind, is the most effective and the worst and the most dangerous bioterrorist. And how you respond to it from the standpoint of the development of vaccine platforms is indistinguishable from what we would do to try and isolate an agent that someone deliberately released, how we would characterize it, and how we would try to make a vaccine.

So the answer to your question, which is a very good question, is absolutely yes, we would be doing the same thing from a fundamental research and clinical trials standpoint.

Dr. LURIE. And I would very much concur with my colleague. Our preparedness planning, we try to make all hazards, you know, whether it is natural or man made, whether it is a weather event or a pandemic. Many of the things you have to do to respond are the same. And at the same time, we are working hard to do the advanced development, to have flexible large-scale manufacturing capacity so that when we need to produce a new kind of countermeasure, regardless of what it is, we will be able to do it. But we are still dependent on where we are with the same infrastructure, the same technologies, the same workforce, all of those kinds of things.

From the public health perspective, I also want to say if you want to be able to respond to an emergency like this you have got to be able do it day to day. And one of the concerns is the more we whittle away at this infrastructure, whether it is at the local level or the State level or the Federal level, the less we will be able

to do that, back to Ms. DeLauro's point about really needing a huge infrastructure project for this country.

ALL HAZARDS APPROACH

Dr. FRIEDEN. Absolutely. It is the same system. In fact, at the CDC it is granting mechanisms that are used for preparedness and response to terrorism that have been used to funnel money or provide money to States and localities. It shows the wisdom of the all-hazards approach, the dual-use approach. You want people who are addressing problems today to get in the practice of doing that both so that you can have them well practiced, and also so that if you do not have an emergency or it takes a couple of years, you are making excellent use of that money and those resources to protect people's health day in and day out.

Dr. LURIE. I think it is also important to point out that many of the investments that we have made in preparedness really have benefits in day-to-day public health practice. And I do not want us to lose sight of that. So it is not just if nothing happens.

Even if I look at the use of incident command in public health, so many health departments around the country now use this for routine outbreak investigation. And they tell you that it goes better and faster. And you can find example after example after example of where this investment pays off. There is just not enough of it.

Mr. OBEY. Mr. Tiahrt, do you have any wrap-up questions?

N95 RESPIRATORS

Mr. TIAHRT. I have a couple questions. First of all, is there any scientific evidence that an N95 respirator is more effective than a common surgical mask?

Dr. FRIEDEN. This is an area of considerable debate and discussion. CDC and the Department of Labor, OSHA, requested that the National Academy of Sciences', Institute of Medicine undertake an independent and rapid review looking at that specific question, and without reference to feasibility or cost.

The Institute of Medicine, or IOM, did that review and recommended two things. First, the use of N95 masks, given the level of uncertainty with theoretical reasons that would suggest that they may be superior, and second, they are conducting additional research.

Mr. TIAHRT. Theoretically, they look better or they are more highly tech and so, but we really do not know. We could use common surgical masks at least as a backstop, correct?

Dr. FRIEDEN. In our guidance——

Mr. TIAHRT. We do not know what percentage it is whether or worse than an N95 or if it is the same.

Dr. FRIEDEN. In our guidance we give outlines of what can be done if there is a shortage of N95s.

Mr. TIAHRT. But we do not have any scientific evidence that says an N95 is superior. Correct?

Dr. FRIEDEN. I would agree with that.

VACCINE DEMANDS

Mr. TIAHRT. Okay. Now what is the need? How many of these vaccines do we need?

Dr. FRIEDEN. Masks?

Mr. TIAHRT. No, no, I am switching to vaccines. We have a problem of getting vaccines. I listened to the whole hearing. I just do not know how many we need. How many do we need?

Dr. FRIEDEN. We would like to have enough vaccines so that everyone who wants to be vaccinated——

VACCINE SUPPLY

Mr. TIAHRT. What is enough? Is that one million? Is that 100 million? Is that 300 million?

Dr. FRIEDEN. It would depend on demand. We want there to be enough for everyone who wants to be vaccinated to be vaccinated.

Mr. TIAHRT. So we do not have a goal? What is our goal? We do not know the demand, but we have a goal, I would assume. We are building some, we are buying to some level. What is that level? 159 million in the priority groups?

Dr. FAUCI. In the five priority groups.

Dr. FRIEDEN. But we know that many people——

Dr. FAUCI. Will not want it.

Dr. FRIEDEN [continuing]. Will not want it.

Mr. TIAHRT. So 159 million is what we need.

Dr. FAUCI. If everybody in the priority group wanted a vaccine, that would be 159 million.

Mr. TIAHRT. And how many do we have on hand today?

Dr. FRIEDEN. 32.3 million.

Mr. TIAHRT. 32.3. So we need 127 million theoretically.

Dr. FRIEDEN. In the best of situations, we get about a third of people who are under 65 and about two-thirds of people who are over 65 to get vaccinated against seasonal flu each year.

Mr. TIAHRT. So what do I take away from the 127 million that we need? How much do I take away because of that? Do I take away all of it? It is not all of it, is it? We do need something, right?

Dr. LURIE. So maybe I can come at this from the other perspective. When we started this, we said that we would buy or put in orders for enough bulk vaccine to get ultimately to about 250 million doses if we needed it. Now, all of that does not have to get made and not all of it needs to get filled and finished.

Mr. TIAHRT. So it is not 250 million or it is 250 million?

Dr. LURIE. No, we have had a staged approach. That was when we thought we were going to need two doses for everybody.

Mr. TIAHRT. Now it is less because we do not need two doses for everybody.

Dr. LURIE. Right. So where we always want to be is ahead of ourselves when the production catches up, and the antigen that is in big vats, and figuring out how much we need to fill and finish and put in vials based on the demand, and always have enough, eventually, and that the goal is to always have enough to meet that demand.

We also want to be in a situation where we are good stewards of society's resources. And so the best way to do that is to hold a

bunch of those in that bulk form, not in vials, until we can anticipate that demand and we are going to need it. Because then that can be turned back into seasonal vaccine.

Mr. TIAHRT. I guess it is a little confusing. We know we have a demand, but we do not know how big the demand is, so we do not know how many to put in vials versus bulk. So what are we working towards?

Dr. LURIE. So far, we are putting as much in vials as we can until we get a signal that demand is really starting to drop off.

VACCINE MANUFACTURING

Mr. TIAHRT. I can see why this has—I mean reporters are having trouble not saying that this is a crisis. It is like we cannot define where we are going particularly, and so we do not know if we are there.

Dr. FRIEDEN. I think as Dr. Lurie said, we are telling the manufacturers to make as much vaccine as they can safely as quickly as they can.

Mr. TIAHRT. But we have five manufacturers, one in America, none of them owned by American companies. Some of them are in Australia, owned by Australian companies that have diverted their supply.

Can you see the reason why people are a little bit uncertain about this? None of these are controlled by American manufacturers. In fact, the one manufacturer in America is actually owned by a French company. What if the French said, gee, we got to have that stuff, ship it over here. We are left with what for a fallback? I mean we have made it so difficult for an American company to own American pharmaceutical manufacturing capability for this vaccine that we have pushed it all over shore, either in ownership or in physical location.

So I can understand why people are very upset. And it is not just the fact that we have not thrown enough government money at this. We spent lots of money. It is the fact we have got a structure in place created by our Federal Government that makes it onerous for people to manufacture or have a facility that manufactures this capability in America.

Dr. LURIE. Certainly the structure and all the incentives that have been in place over decades have led us to the situation that we are in. We are all confronting the problem.

Mr. TIAHRT. Yeah. It is just like we are worried about the alligators. We forgot we started out to drain the swamp. I do not think we are after the real problem here. We are responding to an emergency again. And Mr. Obey made this. But I think there are some underlying structural problems in our economy that have put us in this situation and forced manufacturing overseas or to a foreign-owned entity. And I think until we get to the root cause of that, we are just going to be in this problem 5 years from now and 10 years from now and 15 years from now. We will be dependent on somebody else as a society, we will be dependent on some foreign entity or foreign government to say, okay, you guys can have some now.

Do you see any other way about it? I mean a French-owned company is the only geographically-based in America manufacturer. Is that not correct?

Dr. LURIE. That is correct. But let me also, just so people do not have the misconception that the French Government can, you know, suddenly decide——

Mr. TIAHRT. That is what the Australian Government did.

Dr. LURIE. That is because it was being manufactured in Australia.

Mr. TIAHRT. So you are saying that if the French Government did tell them you got to send it over here we could stop it at the border?

Dr. LURIE. There is something called the Defense Protection Act that would ensure that that vaccine would stay in this country. And part of the reason that we really need to have the manufacturing capacity in this country is so that we can use those mechanisms to ensure that we have vaccine when we need it.

Mr. TIAHRT. I can see why people are concerned, Mr. Chairman. We do not have the ability do what we need to do.

Mr. OBEY. I would simply say that four and five years ago, when we were talking about this problem, we focused with Secretary Leavitt on the issue of what role the Federal Government could play in regularizing production by assuring manufacturers that if they did locate in this country and if they did produce that they would have a purchaser of last resort so that they knew that they would not be stuck with millions of doses if there was no demand in any given year. And it seems to me until we work out that kind of an arrangement, we are going to be stuck.

So to me it is the same question we raised with Secretary Leavitt four years ago. When are we going to get with it and try to set up that kind of an arrangement?

Any comment? You are going to duck it now?

Mr. TIAHRT. In the one facility, when we asked them to manufacture stuff for us, do we waive any liability on their part? I was just watching TV last night and there was another ad saying if you have been harmed by this drug, call this number. And there is a lot of advertising going on about how we can get to these drug manufacturers and sue the pants off them. So when we ask people to do something like this, which is, you know, rather vague whether on how many doses are needed and what the side effects are, we just kind of go on percentages, and more than 50 percent, it is not risk free. So do we give them any liability waivers for this or do we just—we do?

Dr. LURIE. Yes. So these manufacturers——

Mr. TIAHRT. So if we give them liability waivers it makes it easier for us to make things in America. Is that what we are saying?

Dr. LURIE. This is something called the PREP Act that provides liability coverage other than willful misconduct for manufacturers all the way through to the people who put the shot in the arm.

Mr. TIAHRT. So we protect them liability-wise. And that is a good thing. Otherwise we would not have the manufacturing here?

Dr. LURIE. There are a lot of reasons we do not have manufacturing here. That has certainly been a big obstacle. If we did not

have the PREP Act in place, I am not sure we would have vaccine right now at all.

Mr. TIAHRT. Good point. Very good point. I think that goes to the underlying causes of why we are in this situation. We have forced manufacturing overseas because of liability, because of a tax structure, because of a regulatory structure that is onerous, because of our inability to be energy independent. And then we wonder how we get in these situations. We say, well, we did not throw enough money at it.

No, we put a structure in place over the last generation that has systematically forced jobs overseas. Now, to cover for it we are going to give these guys liability protection. But that is just one of probably 8 different or 12 different things that have caused people to make the conscious decision as stockholders to not invest in America, because it is just too costly. It is just too difficult. It is just too hard.

So instead, they move their production to Australia or someplace else. And not knowing the complete history, I can tell you the structure problems, but I cannot tell you the complete history. But that is the bottom line is we have done this as a government. We have made it so onerous for them to make stuff here in America that now in order to keep what we got and to get the vaccines we have we have to waive the liability requirements.

One of many infrastructure problems that we need to correct, and that is the job of Congress to correct, not you guys.

I appreciate what you do, and thanks for coming and testifying. And you know, we are dependent on you. Godspeed. Thank you, Mr. Chairman.

Mr. OBEY. Let me simply point out that in the last supplemental, I believe, we also provided a process under which a government could set up a compensation system to assist anyone who had been injured by those vaccines. So I think we have taken significant actions to try to deal with that problem.

Did she leave? I guess Ms. Roybal-Allard has gone. And she wanted to ask two questions. I will put them in the record, if there is a record. That is right, there is not a record. This is a briefing. Old habits die hard.

Well, thank you all for coming. I appreciate it. It has been very useful.

Dr. FRIEDEN. Thank you.

[Whereupon, the subcommittee was adjourned.]